INSTRUCTION MANUAL

READ THE INSTRUCTION MANUAL BEFORE OPERATING THE DEVICE TO PREVENT ANY SAFETY RISK AND DEVICE DETERIORATION

CE 0459

EC REP

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This user manual is made for the WAVES system

For technical, clinical, or commercial support, please contact our Clinical Support / Customer Service team.

Technical or Clinical Support

Waters Medical Systems (WMS) technicians and clinical support staff are available 24 hours per day to assist customers.

Customer Service

WMS provides toll free telephone support to assist with product information. To place an order for a perfusion device, to order replacement parts, or to order disposable components call Customer Service. The following numbers can be used for technical and non-technical support:

800-426-9877	24- hours support number
00-1-507-252-3784	International
1-507-252-3700	Facsimile
www.igl-group.com	Website information
contact@wtrs.com	Email

Manufacturer :
WATERS MEDICAL SYSTEMS LLC
2112- 15th St NW
Rochester, MN 55901-6117 USA

Returning Equipment

Should a customer need to return a device for maintenance, or request a replacement disposable part, please contact us using the 24 Hour Support Number. Please return any disposable part that needs to be replaced to WMS for inspection.

Many questions can be answered by telephone and we suggest customers call before shipping a device or part to WMS. If you believe you need to return your instrument to WMS, call Customer Service for a return #and shipping information. Return the WAVES to WMS in the original shipping packaging. The original packaging will minimize delays and shipping damage. It is strongly recommended the WAVES be insured for full purchase price in case of damage or loss. Waters is not responsible for return shipping charges, damage, or loss. All parcels should be shipped to our Rochester street address.

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

Instruction manual revision: 3070055.001 Rev. 6 2012-11-13
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WARRANTY

Waters Medical Systems warrants that during a period of one year from date of shipment from the factory, each new instrument sold or manufactured by Waters is free from defects in material or workmanship under normal installation, use and service. Waters Medical Systems agrees that any such defect shall be repaired or replaced at Waters discretion, provided the part is delivered intact to the factory for examination with shipping costs prepaid by the owner. Exceptions to this warranty include items or parts that require periodic replacement or calibration consistent with normal use and instructions. Such items or parts are not covered under this warranty.

This warranty does not extend to any instrument, which has been subjected to negligence, accident, abuse, misuse or other improper operation, or has been tampered with or altered or repaired by anyone other than an authorized service representative of Waters Medical Systems.

The purchaser assumes all liability for all claims, losses or damages incurred by the use or misuse of the instrument, when placing and accepting delivery of an instrument, supporting parts or disposables.

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INTRODUCTION

The WAVES is a two-part kidney preservation and evaluation system which includes a control unit for monitoring pulsatile perfusion of one kidney. The system is comprised of: 1) a control unit (further referenced by WAVES or WAVES control unit) and 2) a sterile, disposable, single-use cassette (further referenced by Waters Cassette Module or WCM) to aseptically store the kidney.

Finally, a "machine perfusate" designed for use in a perfusion device is added to the WCM and circulated though the kidney during the preservation period and during transport.

1) The WAVES control unit is a self-contained unit for monitoring the perfusion and/or transportation of the kidney. The control unit is necessary for the WCM cassette to function properly.

2) The WCM cassette is an organ container which employs a circulation system consisting of the organ chamber, venous and arterial reservoir, bubble trap, integrated temperature and pressure sensors, membrane oxygenator, heat exchanger and pulsatile pump head. The cassette provides circulation of up to one liter of perfusate to one kidney. The WCM is specifically designed for the control unit and no other cassette will fit into the control unit.

Contents Included

- WAVES Control Unit
- Instruction Manual
- Batteries (4)
- Power Cord
- USB Flash Drive
- Adapter for air port

For a complete list of available accessories for the WAVES, please contact Waters Medical Systems Customer Service listed on page 2.

STATEMENT OF INTENDED USE

The WAVES is intended to be used for the pulsatile hypothermic machine perfusion of kidneys for preservation, transportation, and eventual transplantation into a recipient.

Description:

The device provides a simple and efficient method of organ preservation using a physiology based pulsatile pump, and membrane oxygenator. The system utilizes hypothermic temperatures and a machine preservation solution to provide organ preservation.

The device is designed to preserve one kidney by perfusing a machine perfusion solution through the organ's artery(s) while maintaining stable pressure, oxygenation, flow and temperature. The device is not to be used for direct contact with any patient. Clinical experience has shown that hypothermic pulsatile preservation of kidneys for transplant is a safe, effective, and cost efficient means of preservation.[1,2] Previous preservation system models of this type, developed by WMS, have safely preserved thousands of kidneys for transplantation.

Perfusion parameters are controlled and displayed by the WAVES. These parameters are: Systolic, Mean, and Diastolic pressure, Flow, Temperature, and Renal Resistance. Systolic pressure is set by the user and then controlled automatically by the WAVES (in AUTO mode) or by the user (in MANUAL mode). Other perfusion parameters (flow and temperature) are measured by the WAVES and displayed continuously for evaluation by the operator. Renal resistance is calculated by dividing the mean pressure in mmHg by the flow in ml/min and also displayed continuously. Mean pressure is calculated using the formula:

$$\text{Mean} = (\text{Sys} + 2 \times \text{Dia})/3$$

Where: *Sys* = systolic pressure and *Dia* = diastolic pressure in mmHg.

WAVES components, accessory products, and disposable supplies are intended to be used for pulsatile perfusion of the kidney. These products are to be used in accordance with this instruction manual, associated WMS documents, and accepted medical standards.

Only accessories and supplies purchased from or recommended by WMS are to be used with the WAVES. In addition, only preservation solutions designed specifically for pulsatile perfusion of the kidney should be used with the WAVES. Use of supplies other than WMS may result in less than optimal performance and may invalidate the warranty.

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1 "Immediate Function and Cost Comparison Between Static and Pulsatile Preservation in Kidney Recipients", J.A. Light, F. Gage, A.E. Kowalski, T.M. Sasaki, C.O. Callendar, Clinical Transplantation 1996; 10:233-236.

2 "Efficacy of Clinical Cadaver Kidney Preservation by Continuous Perfusion", R.M. Hoffman, R.J. Stratta, H.W. Solinger, M. WarningsKalayoglu, J.D. Pirsch, F.O. Belzer; Transplant Proceedings, Vol. XX, No 5 (October) 1988; pp 882-884.

PRECAUTIONS

- The WAVES control unit should be operated by trained personnel who have read the instruction manual.
- Always inspect the unit, power cord, WCM perfusion circuit, and all accessory cables for damaged connectors or wires prior to use. The use of any damaged accessories or cable may cause a loss of signal or interference. Use only manufacturer approved accessories.
- It is recommended users transport the WAVES using only the WAVES transport bag.
- The user must remove the WAVES control unit from the WAVES transport bag for clinical use.
- Prior to clinical use, one should position the WAVES control unit on a flat and level surface at a height which provides an easy view of the display. The user should provide adequate space to open the unit's doors. Easy access to the power switch, network cable, USB port, and other accessories is recommended.
- Cold water and ice are necessary for unit operation.
- Do not block the vent holes on the left side of the unit, the front portion of the unit, or under the device cabinet.
- Do not autoclave or sterilize the WAVES. Clean the WAVES using non-corrosive, non-acidic antiseptic cleansers which are safe for plastics and painted surfaces.
- Check ice and battery levels regularly. Completely charge the batteries and refill the ice reservoir prior to transport.
- Use only ice and water in the reservoir for cooling purposes.
- Keep the device upright at all times.
- Do not expose the unit to direct sunlight and extreme temperature (hot or cold).
- Beware any moving mechanical part, such as the doors, pulse head, and door latches.
- Follow air transport regulations when transporting the device.
- Visually inspect each WCM cassette to make certain all connectors, sensors, and associated tubing are secure before attaching the cassette to the WAVES.
- Check expiration dates on all disposable equipment and solutions prior to use. Do not use any expired products with the device. The use of expired product may impact the performance and the safety
- Secure the kidney, cassette covers, and lids before moving or transporting the device.
- During clinical transport (with an organ being perfused), the device should be transported with an A/C power cord and the recommended number of charged batteries in the unit.
- Make sure all renal arteries are properly cannulated and perfused.
- Make sure the cassette is sealed, appropriately labeled, and not leaking during perfusion.

- Disposable products provided by Waters Medical Systems are sterile. Do not resterilize or reuse disposable products.
- Training and research products (WCM disposables and machine solution) are available from WMS but should never be used for clinical perfusion. These components are clearly marked “NON-STERILE” and are not intended for clinical use.
- Always use universal precautions and aseptic procedures with the WAVES perfusion device, organs, specimens, and perfusate.
- Use only solutions designed for hypothermic pulsatile perfusion.

WARNINGS

- **During non-clinical transport (no organ being perfused): DO NOT SHIP THE WAVES TO WMS WITH THE LI-ION BATTERIES INSIDE THE UNIT. FIRE OR DAMAGE MAY RESULT TO THE WAVES AND VOID WARRANTY.**
- **SHOCK HAZARD.NOT USER SERVICABLE. WARRANTY WILL BE TERMINATED.**
- **EXPLOSION RISKS. DO NOT USE THE WAVES IN THE PRESENCE OF FLAMMABLE ANESTHETICS.**
- **USE ONLY HOSPITAL GRADE POWER CORD WITH GROUND.**
- **THE WAVES MUST BE CONNECTED TO A RECEPTACLE MARKED HOSPITAL GRADE.**
- **USE PROPER LIFTING TECHNIQUES AND THE WAVES TRANSPORT BAG TO LIMIT POTENTIAL INJURY.**
- **USE UNIVERSAL PRECAUTIONS AND ASCEPTIC TECHNIQUES TO AVOID CONTAMINATION OF THE KIDNEY PRIOR TO OR DURING PERFUSION**
- **BE AWARE THE DEVICE, USED DISPOSABLES AND SOLUTIONS, AND THE KIDNEY CAN CARRY PATHOGENS. USE UNIVERSAL PRECAUTIONS TO PREVENT EXPOSURE TO THE USER. CLEAN THE DEVICE AFTER EACH USE.**
- **USE PROPER PERFUSION PRESSURE AND DO NOT OVER PRESSURIZE AN ORGAN.**
- **DISPOSE OF CONTAMINATED CASSETTES AND SOLUTION USING UNIVERSAL PRECAUTIONS AND LOCAL PROTOCOLS TO PREVENT POTENTIAL EXPOSURE TO OTHERS.**

THE WAVES PERFUSION SYSTEM

The WAVES perfusion system is a two part system consisting of a control unit and a single use disposable cassette which contains the kidney and machine preservation solution.

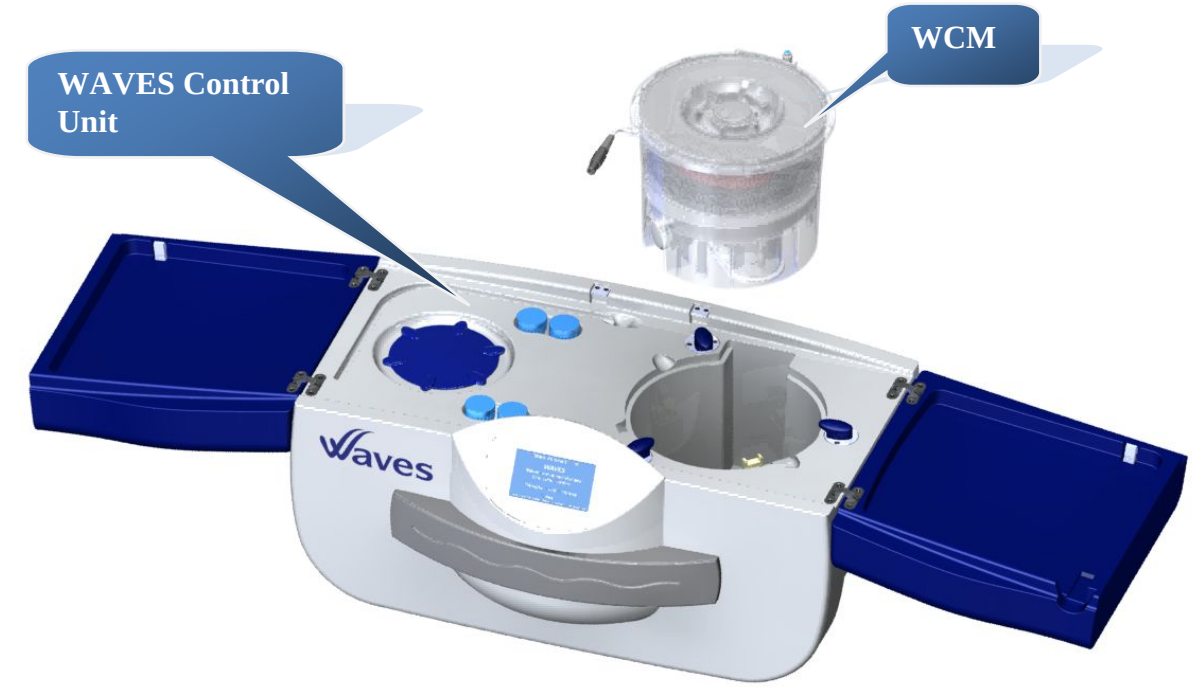


Figure 1: **The WAVES perfusion system: front view**

Figure 2: **The WAVES perfusion system: back view**

THE WAVES CONTROL UNIT

The WAVES control unit (Figure 1 and 2) regulates the pulsatile perfusion sequence. The WAVES will perfuse the organ with machine perfusate, and monitor real-time pressure, flow and temperature of the perfusate. Further, the control unit will display all parameters for visual confirmation of perfusion activity. The control unit will provide trend data to help the evaluation of the kidney prior to transplantation.

Data Storage

The user can select data to view in the display and/or download onto a USB flash drive.
The WAVES control unit has a USB port for data transfer and storage onto a flash drive on the back of the unit. The user should determine if the flash drive is recognized by the unit prior to data transfer.

Figure 3: WAVES USB data storage

Network Connectivity

The WAVES system permits the user to view the current perfusion data on a network or smartphone when the unit is properly connected to a network. The user will need to work with local IT support to make certain the device can be accessed by the local network.

After connecting the WAVES system to a network using an Ethernet line, the user can monitor the WAVES using a web browser. THE USER CANNOT CONTROL the unit or make any adjustment over any network.

The WAVES web display will provide current perfusion parameters such as pressure, temperature, renal resistance value and alarms. The total perfusion time can be monitored. A perfusion report may be printed.

The WAVES has an Ethernet port on the back of the unit for network connection.

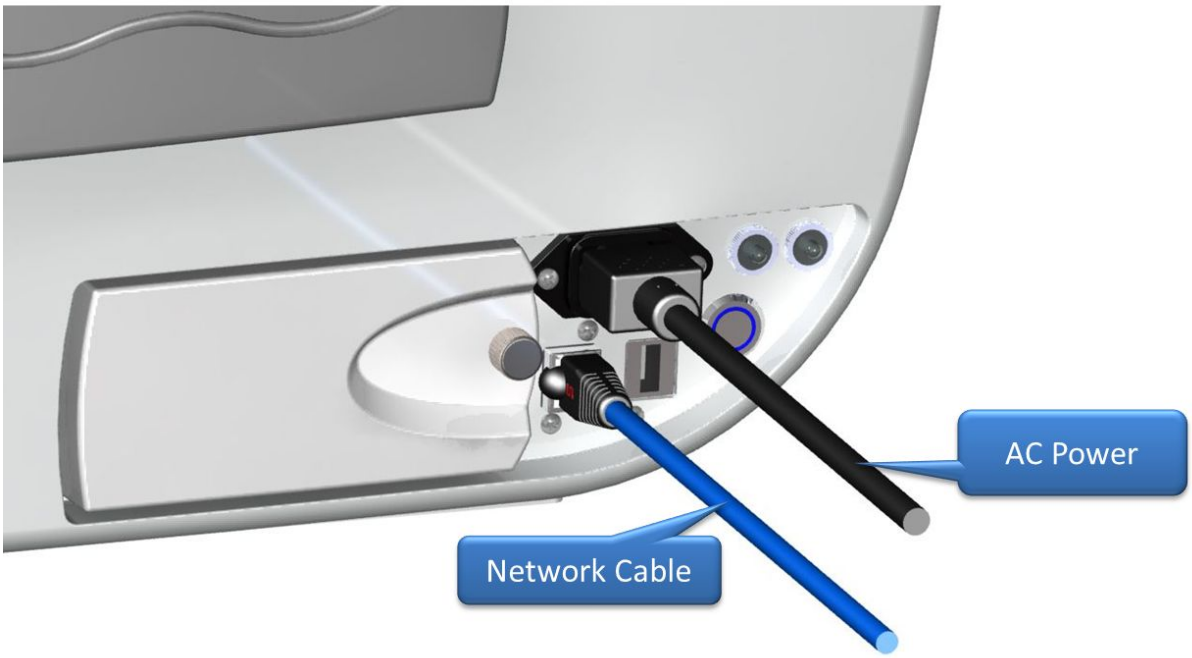


Figure 4: WAVES network connectivity

Power and Batteries

The WAVES operates on 100 to 240VAC, 50 to 60 Hz, or rechargeable Lithium-Ion battery(s) to provide continuous power. Two circuit breakers will disconnect the mains upon an internal short condition.

A Main power switch is available to start and/or stop the WAVES. The power switch must be held for a short period to start the device. The start button will glow “blue” when the unit is powered on.

Battery operation lasts up to 12hourswith four fully charged batteries.AC mains must be plugged in to “re-charge” batteries.

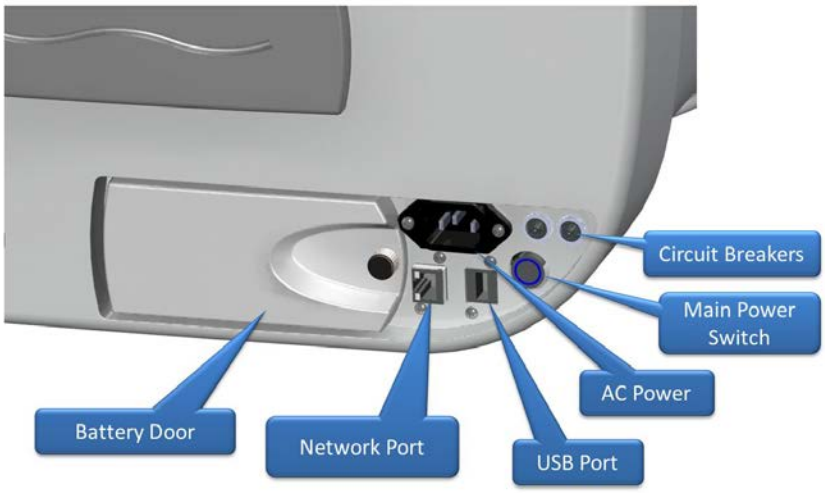


Figure 5: WAVES back panel

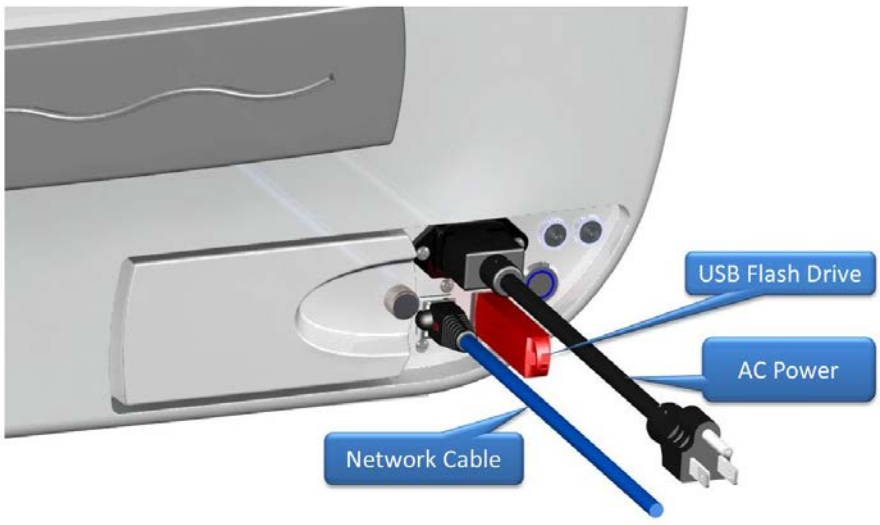


Figure 6: WAVES back panel connections

Use only a hospital grade AC power cord as provided.

Use only batteries recommended by WMS. Do not substitute batteries. You have access to the batteries by a door on the back of the device. No tools are needed to open the door. To access the batteries, unscrew knob as shown in **Figure 7** and remove the door. Make certain the batteries are in position and making contact with the unit prior to use.

The batteries can be placed in the compartment in only one position. See **Figure 7** for battery installation. It is recommended to have spare batteries before transport.

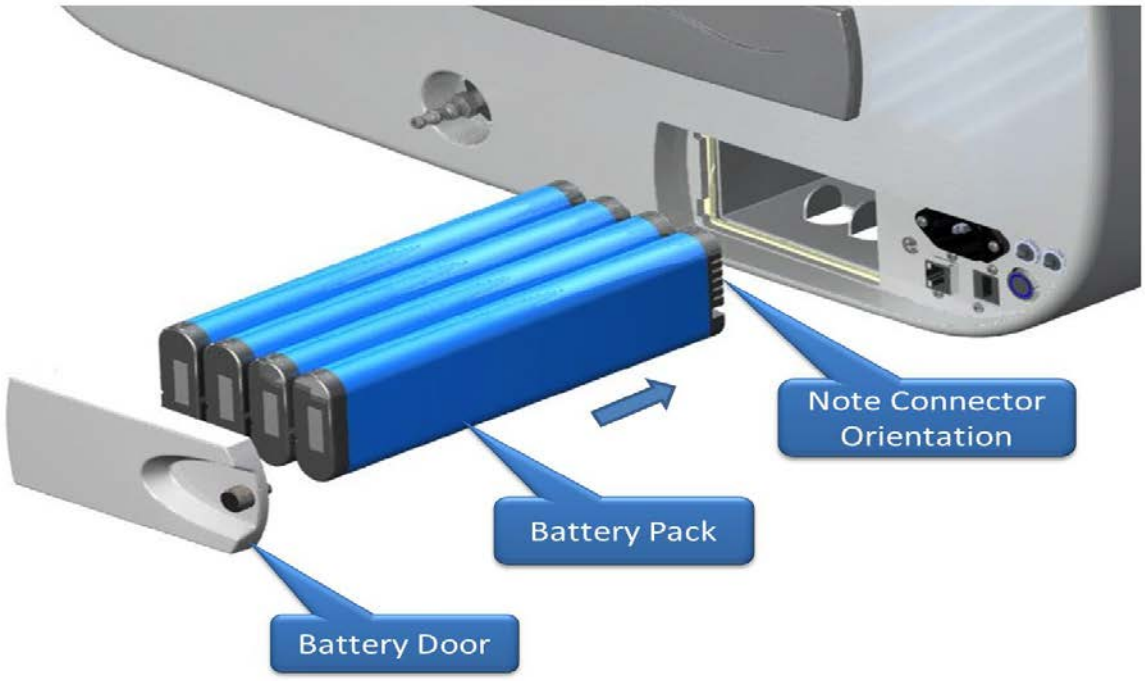


Figure 7: WAVES battery

Display / User interface

The display touchpad / user interface screen allows the user to control the unit and provides the user with continuous controls and updates on the perfusion parameters. During normal operation the display will provide real-time perfusion parameters and will notify the user with information if problems occur during setup instructions or as a result of an alarm message. The display also offers other menu options, including password controlled technical menus, and perfusion trending options. The display provides current information in numerical format which includes systolic, mean, and diastolic pressures, flow from the kidney and temperature of the perfusate and renal resistance of the kidney. The perfusion measurements will be displayed at all times during an alarm. The alarm system will signal an audio as well as a visual alarm for the user in selected alarm conditions. See page 88 for alarms and their descriptions along with troubleshooting tips.

Figure 8 : WAVES touchpad display

Pressure regulation

The WAVES control unit has variable stroke volume control allowing the operator to adjust the motion of the pulsatile pump. By adjusting the pressure using the touchpad screen (see software and control description beginning on page 36), the volume of perfusate delivered by the pump to the kidney is increased or decreased along with a corresponding increase or decrease in pressure.

WAVES configuration

The WAVES system has two configurations, ‘closed’ and ‘open’:

- Closed configuration (Figure 9): For storage, clinical organ perfusion or transport. This configuration will be used during perfusion to increase heat exchange, and reduce the loss of ice during perfusion. The closed configuration also provides maximum protection for the kidney.

  When not in perfusion mode or during storage, the unit should be placed in the transport bag. The bag is vented and can be used for short transport periods during perfusion, but the unit should be removed from the bag immediately when the unit reaches its desired location or frequently during any extended perfusion transport period to prevent heat build-up.

- Open configuration (Figure 10): To place kidney in the cassette and begin perfusion, to visualize the kidney on the device, or sample perfusate. In general, the organ should be perfused with the devices lids in the closed position. This open “clinical” configuration gives the user space to work. The two doors may be used as work spaces covered with the sterile drape during placement of the kidney.

Figure 9

WAVES Control Unit in Closed, General Perfusion or Transport configuration

Figure 10

WAVES Control Unit in Open or Clinical configuration (with cassette open for organ placement)

Air port

The WAVES system allows oxygen to be diffused into the preservation solution and thus to the kidney using the oxygenator membrane in the cassette and an air pump installed in the WAVES control unit. No user action is needed for this feature. After the cassette is placed in its compartment, the air circuit is automatically connected and the air pump is started.

An external air port is provided on the back of the device if connection to an external oxygen source is required. The port adapter (supplied) should be screwed into place during use and removed following each use.

Figure 11: WAVES external air port

Temperature regulation

The WAVES system has a coolant reservoir where the user can place up to 5 liters of ice and water. The user should fill the ice water reservoir initially with a minimum of ½ to 1L cold (refrigerated) water. The user should then completely fill the reservoir with and ice. Small "pellet" ice cubes are preferred but ice in any form may be used. The reservoir lid should be closed and remain closed during perfusion and transport.

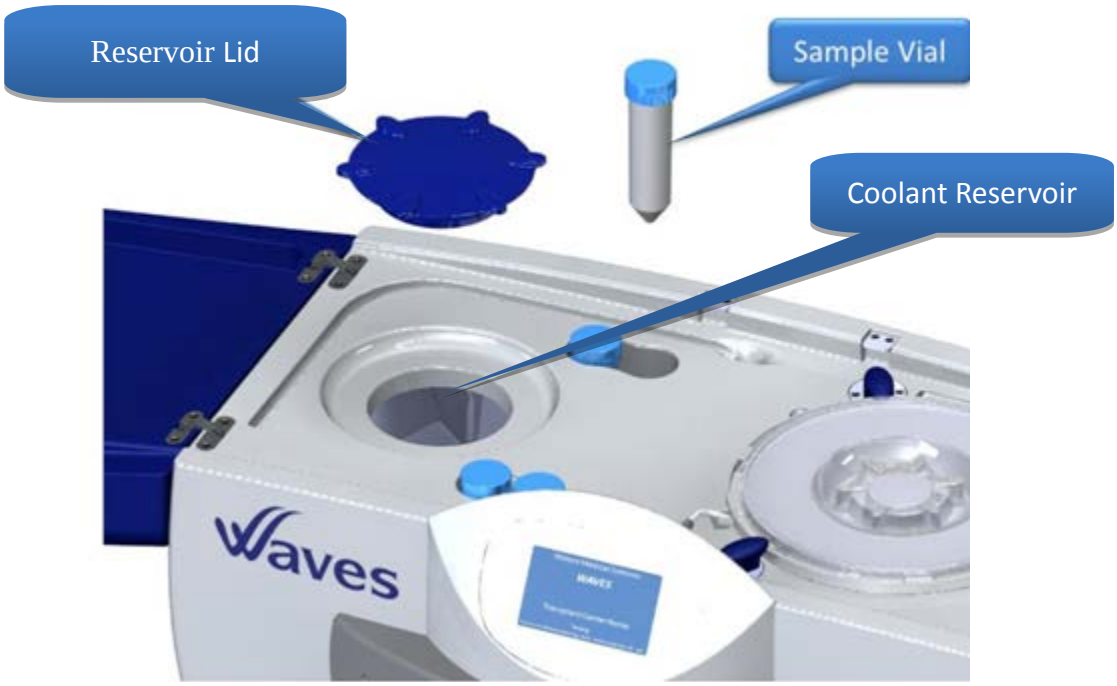


Figure 12 : Ice compartment

A liquid level sensor in the ice reservoir will alert the user in case not enough water is added.

This ice compartment permits temperature regulation in two ways:

- Static heat exchange :
  The cassette chamber is in direct contact with the ice compartment which keeps the cassette chamber environment cool.

- Dynamic and automatic temperature regulation:
  The ice compartment is connected to a cooling pump that transfers water from the tank to the heat exchanger. This heat exchanger is designed in two parts: 1) the heat exchanger base on the Waves control unit (cassette compartment) and 2) the heat exchanger plate on the WCM cassette.

  During perfusion the perfusate circulates through the heat exchanger plate attached to the cassette. The coolant pump circulates water from the ice compartment to the heat exchanger base. After having circulated through the heat exchanger base, the water returns to the ice compartment.

Installing the cassette permits a direct contact between the heat exchanger base and the heat exchanger plate, which provides perfusate temperature regulation.

Two temperature sensors regulate the perfusate temperature to the set perfusion value (usually 5°C +/- 0.5 C). A disposable temperature sensor on the cassette measures the real time perfusate temperature. The coolant pump is turned ON and OFF based on the perfusate temperature. The coolant pump will stop when the perfusate temperature reaches perfusion temperature.

A second temperature sensor in the ice reservoir will provide an alarm message and the pump will stop the coolant circulation if the temperature of the water in the ice compartment reaches 10°C.

THE WAVES CASSETTE: WCM

The WCM cassette, supplied separately, is for single-use and provides a sterile, non-pyrogenic fluid pathway. The WCM cassette is a gravity flow system which houses and protects the kidney during perfusion, and allows perfusate to be circulated through the kidney during perfusion. The organ's position is controlled on the organ platform, and is cradled by a mesh fabric, during perfusion. The organ is immersed in the perfusate during perfusion. After the organ is perfused through the arterial port, the (effluent) flow from the kidney is collected in the organ chamber. The perfusate then flows through the membrane oxygenator and into the heat exchanger. From here the solution is pumped to the bubble trap where it is delivered back through the arterial port to the cannulated kidney. The perfusate then returns to the organ chamber to repeat the perfusion cycle.

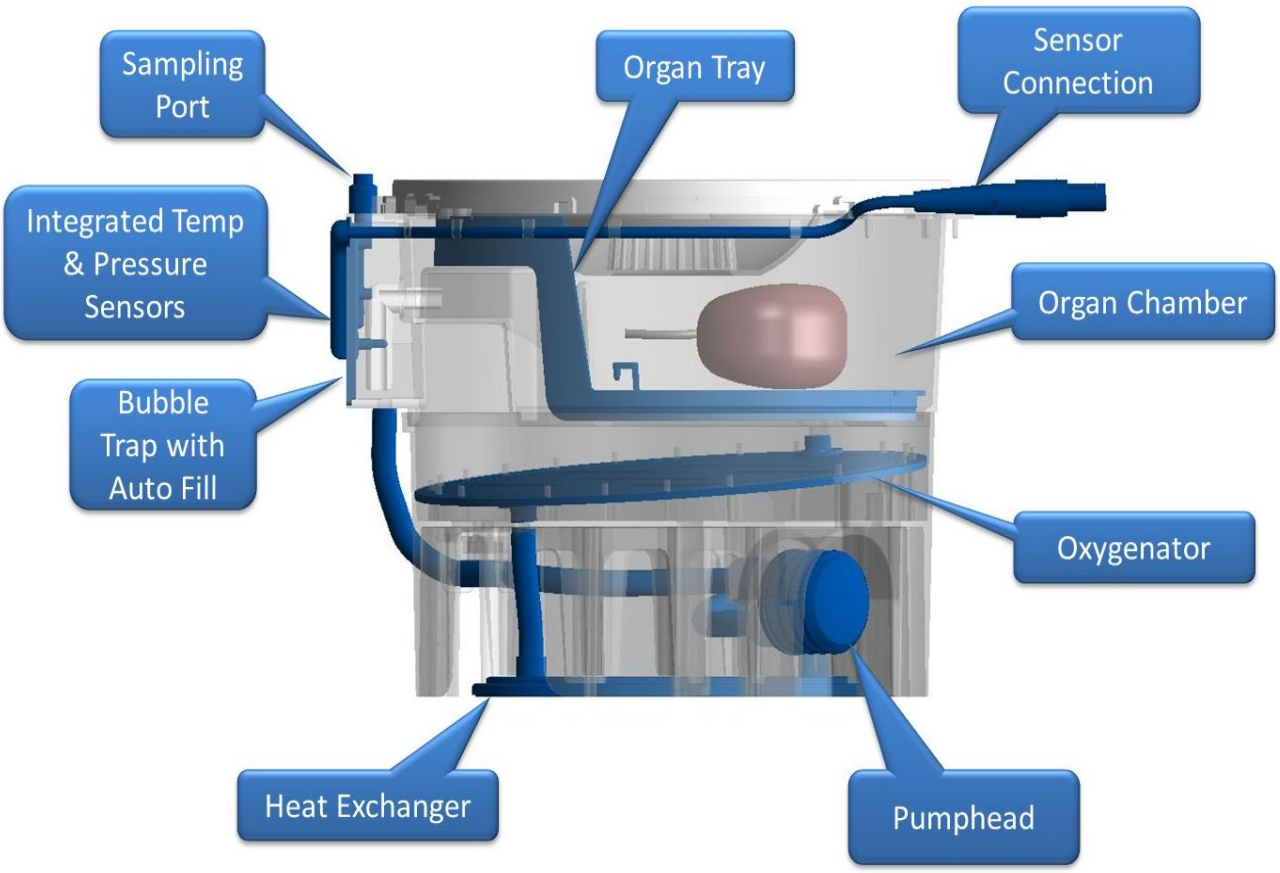
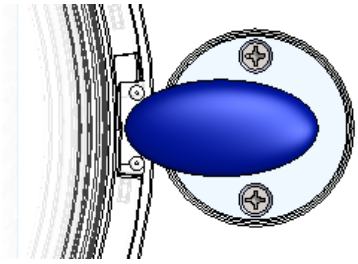


Figure 13: ***WAVES WCM cassette features***

CASSETTE PLACEMENT

Inspect the cassette prior to use for any damages which may have resulted from shipping or handling. From the label on the packaging, the user should note the lot number and expiration date on the local perfusion record. Use aseptic technique when handling the cassette from the packaging. When the user is prompted by the WAVES control unit's display, the cassette can be mounted into the WAVES by aligning the cassette in the appropriate position on the open device surface (see Figure 14 below). The cassette will only fit into the device in one position. When prompted, the user should then secure the three cassette latches mounted on the control unit by rotating them into position between the bumps on the cassette. The pulsatile pump will self-align with the cassette pumphead in the cassette compartment. The pressure transducer, inlet tubing to the ambient air pump, temperature probe, and needleless sample port are integrated into the WAVES cassette. The cassette is designed to be automatically aligned and connected to the flow transducer; therefore, all functions are ready for operation once the cassette is placed properly inside the device. The temperature probe is also integrated into the cassette bubble trap and will control the ice/water reservoir circulation pump and thermostatically maintain the temperature of the perfusate using the cassette sensor connection.

Figure 14: *WAVES WCM cassette installation*



Locking position of cassette latch.

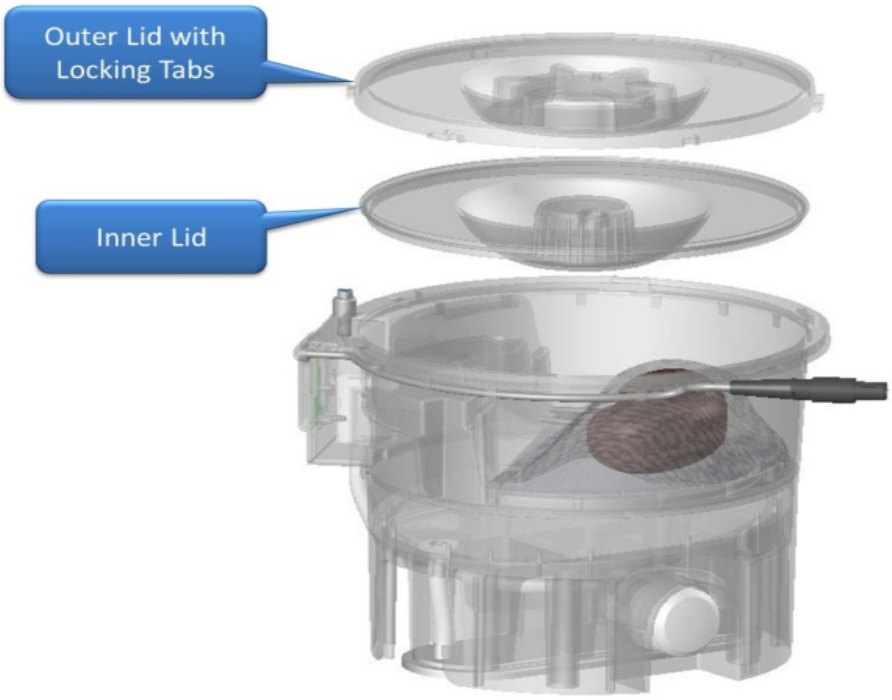


Figure 15: *WAVES cassette lids*

The WCM cassette has two sealed lids to prevent damage or contamination of the kidney from the external environment (see figure 15). During the organ placement process, the user should place the internal lid on the cassette to seal the perfusate in the organ chamber, and then twist and lock the external lid in place. The two lids have a filter to equalize the internal pressure of the cassette with the environment (particularly in cases of dramatic change of pressure). The WCM cassette has been designed to allow for an organ identification label to be attached which should meet federal / local transplant guidelines. The double barrier WCM cassette meets current federal transplant contractor guidelines.

For more information: See UNOS 5.0 policy for verification of organ packaging.

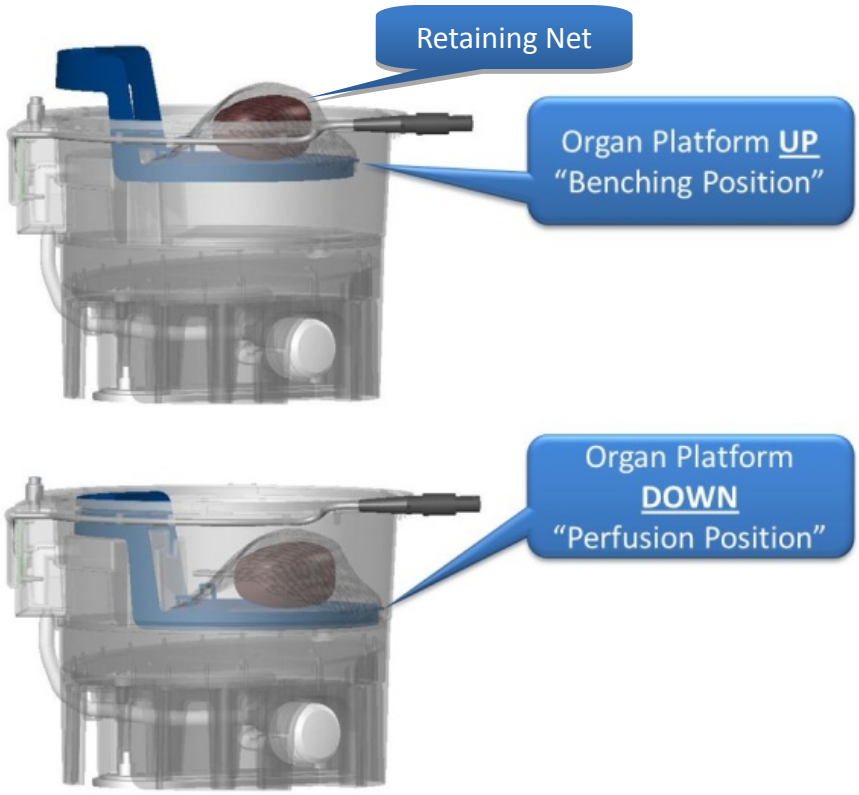


Figure 16: *WAVES organ platform*

ORGAN PLACEMENT

The user should wear glasses, surgical cap, mask, gown and STERILE gloves when touching the mounted cassette or its external lid.

Following the perfusion instructions on the WAVES control display, when prompted to place the sterile drape, the user must use aseptic technique. The user should remove the outer and inner cassette lids and place them on a clean, aseptic surface for later use.

Using aseptic technique, the sterile drape should then be placed on the cassette and locked in place.

With the aseptic drape locked in place, the user should change STERILE gloves and, when prompted by the WAVES control unit display to place the organ, lift the cassette platform to the up position. During organ placement, the platform should remain in the up position. The kidney can then be placed on the cassette platform for cannulation. This position allows the perfusionist direct access to the arterial port and the organ's artery(s). Either the attached silicone tube or multiple artery adaptor (not supplied) is used to attach the organ via its perfusion clamp (or cannula) to the port for perfusion. Note: If the silicone tubing seems too long, it is easily shortened, as necessary, using scissors. After venting air from the clamp / cannula, and renal artery(s), the kidney is attached to the port. The pressure must be monitored and should remain

low at this point. After checking for leaks, the kidney can then be secured with the retaining net on the organ platform. The platform is then placed in the lower position.

To summarize, the platform is removable and has two positions. The Up or benching position permits the user to have easy access to the kidney, particularly during placement for perfusion. The Down or perfusion position must be used during the perfusion. The two lids can be closed only in this position.

BUBBLE TRAP AND SAMPLE PORT

The cassette is fitted with a bubble trap that separates trapped air bubbles from the perfusate prior to the arterial. This helps prevent bubbles from embolizing the kidney. The cassette integrates a disposable perfusate temperature sensor and a disposable pressure transducer in the bubble trap for ease of use. The cassette provides an auto fill capacity and level control mechanisms to regulate fluid height in the trap. WMS recommends the user verify the cassette is in proper working condition, aseptically wrapped and shipped, a needleless sample port is located on the upper portion of the bubble trap. The sample port allows the operator to either infuse drugs into the perfusate or withdraw perfusion samples for analysis. The perfusate level should remain constant at all times for accurate pressure measurements.

PERFUSION PUMPING

The pumping system is made up of a pulse pump piston (in the WAVES control unit) and a bellows pumphead (in the cassette) which provides true pulsatile flow. The pump head includes two one-way valves in series and a silicone bellows pumphead which is compressed and decompressed by the pulse pump piston. The bellows pumphead is self-aligned in the pump assembly.

The WAVES control unit has variable systolic pressure control, allowing the operator to adjust the pulse compression of the pulsatile pump piston on the cassette bellows pump head. By accessing the systolic pressure control buttons on the display, the user can:

- Increase the pump compression, the volume of perfusate from the pump head to the kidney is increased along with a corresponding increase in pressure.
- Decrease the pump compression, the volume of perfusate from the pump head to the kidney is decreased along with a corresponding decrease in pressure.

The flow from the kidney is collected in the oxygenator membrane. During the perfusion, the perfusate is pumped from the oxygenator membrane, passing through the heat exchanger to the pumphead, then to the bubble trap. The flow rate is measured by a flowsensor integrated into the device.

The temperature of the perfusate is regulated using the heat exchanger and a coolant pump. The WAVES system has two parallel liquid circuits:

- Perfusate circuit in the cassette: during the perfusion the perfusate passes through a heat exchanger plate

- Cooling circuit in the WAVES control unit: Cold water (near 0-1°C) is pumped from the ice container and circulates through a heat exchanger base.

The heat exchanger plate and the heat exchanger base are in contact. This contact allows the heat exchanger to cool the perfusate to the desired perfusion temperature. The liquids of the two circuits (perfusate and cold water) are never in contact.

The ice water bath will maintain the hypothermic perfusate temperature for approximately 12 hours at below 10°C at an ambient temperature (around 21°C). After that time, if needed, the coolant will need to be drained and the ice replaced.

DESCRIPTION OF THE WAVES SYSTEM

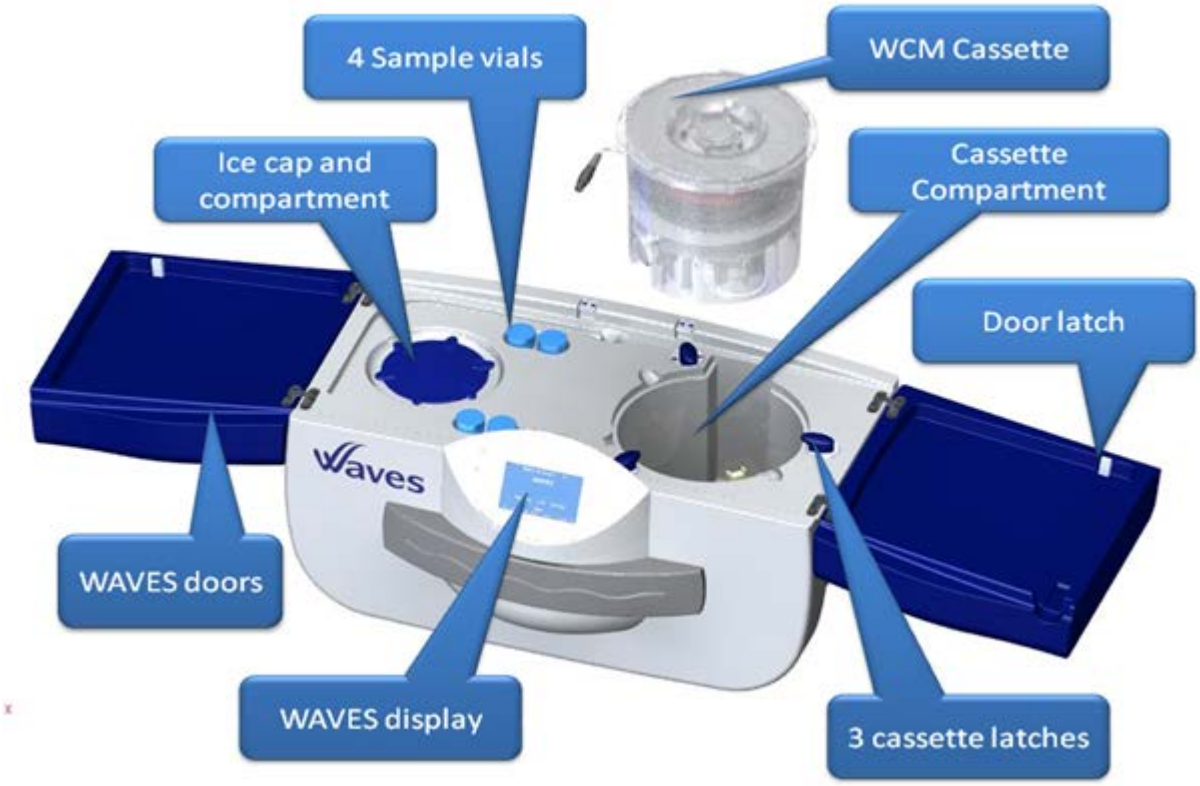


Figure 17: ***Description of the WAVES system***

GETTING STARTED: SET-UP AND CONTROL PROCEDURES

RECEPTION/INSTALLATION

1) Remove the WAVES from the shipping box or transport bag using proper lifting techniques to avoid injuries.
2) Check the presence of all parts and accessories:
    A) Battery doors.
    B) Ice compartment cap.
    C) AC power cord.
    D) Network cable prior to starting the device if you plan to network and monitor the unit (Ethernet cable not provided).
3) To determine that the WAVES is in proper condition, check if the WAVES is in good shape:
    A) Make sure doors are not damaged, hinges are functional and doors latch properly.
    B) Check device body for cracks or damage.
    C) Check external connectors by plug in and then unplugging the A/C power cord, an Ethernet line, and the USB drive.
    D) Examine touchpad display to determine it is not damaged.
4) Install the Waves unit in the designed lab on a flat surface (counter or cart) with access to data access and a power supply.
5) Store the unit in the WAVES transport bag and in a secure area.
6) In either circumstance make sure the following environmental factors are respected for optimal conditions:
    A) Temperature: < 23°C.
    B) Humidity: 50% or less.
    C) AC electrical and network connections available.
    D) Setup area for accessories and disposable parts.

E) Ice and cold (refrigerated) water easily available.

F) Cleaning materials easily available.

G) Setup the device close to the area where the preservation solution is stored.

7) Contact WMS technical support for any problems.

SET UP INSTRUCTIONS

1) Use proper lifting techniques to avoid injuries each time you move the WAVES. Use the transport bag when moving the unit.

2) Check the cleanliness of the WAVES control unit and insure the ice compartment is clean and empty before beginning a perfusion. See page 133 for cleaning recommendations.

3) Make sure no cassette is installed in the WAVES unit.

4) Connect the power cord and network (Ethernet) line if needed before turning on the device.

5) Verify the batteries are in place.

6) Start the WAVES control unit by pushing on the power switch on the back left corner of the device. The power switch lights up (blue) and the display starts.

7) When the unit is fully powered the user can launch a clinical perfusi**o**n session, access history files, drain the ice compartment, check the battery status or access the technical menu After the user makes a choice, the WAVES control unit directs the operator by prompts. After pressing "Clinical Perfusion" the user will follow prompts to insure proper setup.

    A) Enter Username and Perfusion ID using the alphanumeric keyboard on the display/user interface.

    B) Use aseptic technique.

    C) Fill the ice / water compartment as prompted by the WAVES control unit display.

    D) Remove sterile WCM cassette, specimen containers, and sterile drape from box.

    E) Place the cassette in the WAVES prompted by the WAVES control unit display.

    F) Connect cassette cable to the WAVES control unit receptacle.

    G) Secure cassette latches.

    H) The WAVES will automatically prime the cassette.

    I) Allow the WAVES to reach appropriate perfusion temperature.

    J) Change to sterile gloves and remove the outer and inner cassette lids. Place the sterile drape and lock in place. Change into new sterile gloves and place the kidney in the cassette. Attach the cannulated renal artery to the unclamped cassette arterial line. The user can insert a WMS multi-arterial adapter (not supplied) and additional clamps or cannula if needed for multiple renal arteries.

    K) Check for leaks while kidney platform is in up position.

    L) Verify that all parameters are within your stated protocol.

    M) Lower the platform. Closed lids. Label lids.

    N) Use the specimen containers (included) for storing associated materials (biopsies, fluids, etc.) with the organ in the specimen containers and label properly. Place

the containers (up to four) in the appropriate slots on the deck of the WAVES control unit (see **Figure 12** on page 19).

O) Close doors and monitor the organ

P) DO NOT LEAVE WAVES UNATTENDED FOR LONG PERIODS.

END OF PERFUSION

A) Discard medical wastes and disposable parts (cassette, perfusate, disposable cannula) per local protocol using precautions to avoid any contamination.

B) Drain and wipe out the ice reservoir. Do not store the unit with water or ice in the reservoir.

C) Download data to USB drive.

D) Turn OFF the WAVES control unit.

E) Connect to AC power to recharge batteries.

F) Clean the WAVES control unit for next use. See Cleaning instructions on page 133.

TRANSPORTATION

During perfusion, the WAVES system can be transported as needed. The WAVES is made to secure the kidney during transport. WMS provides a transport bag to make easier the transport of the WAVES. WMS DOES NOT RECOMMEND shipping or transporting the device without a trained person to accompany the unit. Users should respect the following guidelines to avoid problems during transport:

1) Secure the kidney using the net enclosure on the organ support platform.
2) Install (close) the two cassette lids and lock the outer lid.
3) Attach an approved UNOS label to the cassette per UNOS guidelines.
4) Close the WAVES doors: be sure the latches are locked.
5) Check the batteries are in place and note they are fully charged.
6) Add ice to completely fill the ice compartment.
7) Place the labeled typing material containers in the proper place on the device deck. Place other accessories and donor documents in the transport bag in appropriate slots.
8) Use proper lifting techniques to place the WAVES in the transport bag.
8) While the transport bag is vented, we recommend the user NOT TRANSPORT the WAVES in clinical perfusion mode for long periods <u>while the device is in the transport bag</u> without opening the zipped lid occasionally to limit heat buildup.
9) You can transport the WAVES on a car or plane seat. In any case secure the WAVES with a restraining device.
10) Keep the WAVES in an upright position to minimize the risk of bubbles or leaks.
11) Control the state of the WAVES during transport if possible.

TRANSPORT BAG

The transport bag is an accessory item, purchased separately, and can provide a safe way to protect / transport the device for short periods. The bag has a zippered lid which can be zip-locked for security and is equipped with wheels, a pull strap, and lifting handles.
The bag allows confidential donor information to be transported in a pouch on the inside of the zippered lid. The information should be controlled at all times while in the transport bag.

Figure 18: WAVES transport bag

WAVES SOFTWARE: DEFINITION AND GENERAL DESCRIPTION OF CONTROLS

POWER ON / OFF (STAND BY CHARGING)

The POWER switch is located on the lower back left panel of the WAVES.

Pushing and holding the ON/OFF switch permits one to turn ON the power of the WAVES and illuminate the display.

The device can be turned OFF using two methods:

- By using the software and the touchpanel of the display (see description for shutdown operation).
- By pushing and holding the power switch for 5 seconds. Batteries are being charged if the WAVES is plugged into the A/C power.

DISPLAY / USER INTERFACE

The user will interact using the touchpad display for all operations. The display is a 4.3" touchpad LCD screen that provides a simple, clear, and user-friendly interface and helps the user during set-up and perfusion operations. The touchscreen allows the user to access menus and to change all perfusion parameters as well as control the different functions of the device.

The following section provides a description of the main screens, which appear on the display of the WAVES.

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Main Menu Screen **37**
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Clinical Screen 2 : Enter Donor/Perfusion ID **39**
Clinical Screen 3a : Confirm Donor/Perfsion ID **40**
Clinical Screen 3b : Error confirmation Donor/Perfsion ID **41**
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Clinical Screen 8 : Cassette in proper position **47**
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Option Screen **69**
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Perfusion History Screen **72**
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Alerts screen **84**
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- **DEVICE INITIALIZATION SCREEN**

When the power is turned on, this initial WAVES screen is displayed during a brief time (two seconds) during internal testing. No action of the user is needed.

The following information will be displayed :

- Name of the manufacturer : **Waters Medical Systems**

- Name of the device : **WAVES**

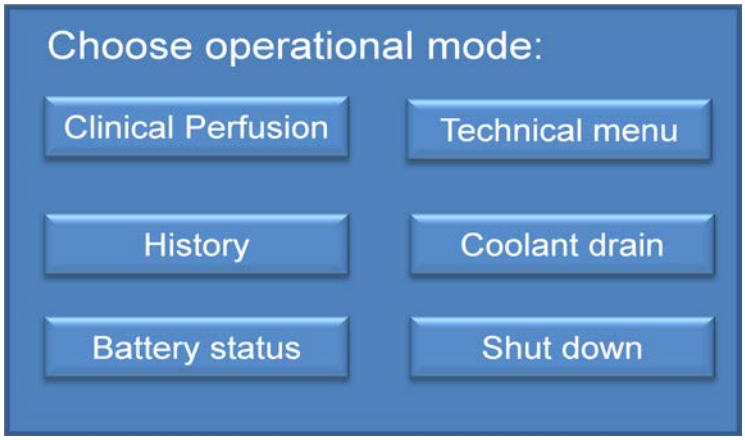
- The unit's owner : **"OPO or Transplant Center Name"**

The user can change the name of the OPO or transplant center by entering the password protected area of the technical menu.

- A message showing the current state of the device during the testing of the main component
- The message that shows the state of the device during the main component testing is "**Testing…"**

  During this autotest, I/O are initialized and pulsatile pump is initialized to its home position.
- Touchpad : Calibration of the touchpad if needed.
- IGL group website*: For more information log onto*: **www.igl-group.com**.

- **MAIN MENU SCREEN**

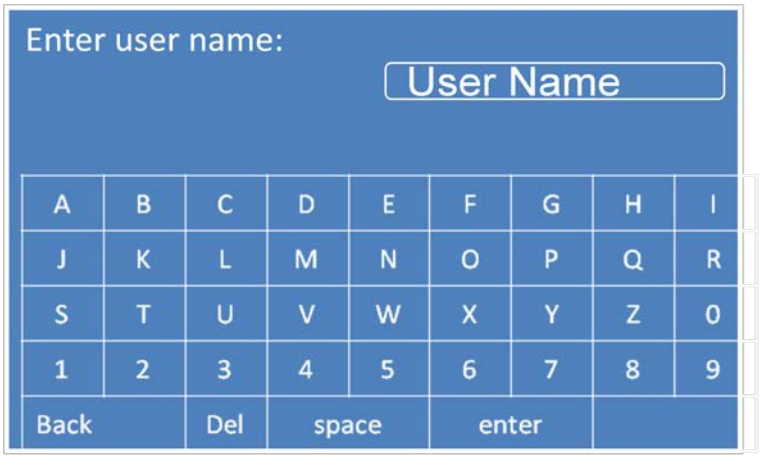


This screen is displayed at startup of the device. The Main Menu gives the user 6 choices. Push one of the 6 buttons to select the desired action:

- **Clinical Perfusion Screen**: To initiate perfusion by going to perfusion screens.
- **Perfusion History**: To access of all perfusion data stored in the device.
- **Battery Status**: To check the charge of each battery.
- **Technical Menu**: To access to the technical settings of the device: secured by password. Only administrator may access the technical menu. If you lose your password, please call WMS technical support to reset.
- **Coolant drain**: To drain the Ice compartment.
- **Shut down**: To shut down the system.

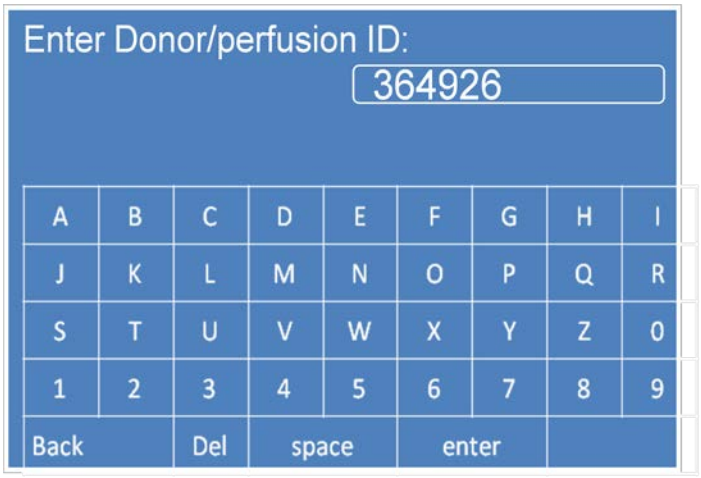
In the following sections, each screen will be discussed in detail and the rational for moving from one screen to another will be provided. A perfusion session can only be started after moving through the steps as described in the following pages.

- **CLINICAL SCREEN 1: USER NAME**



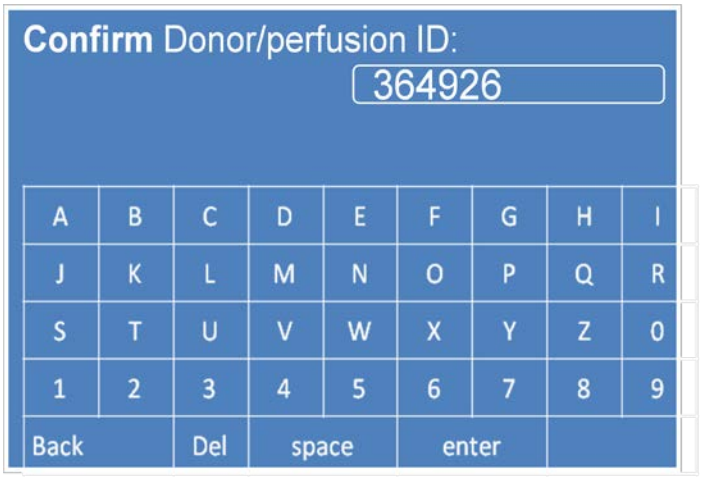
This screen is displayed when you press **Clinical Perfusion** button on the **Main menu screen.**
Please add the perfusionist name to the perfusion trend record using the keypad and press **Enter** to validate.
You can delete characters by pushing on the **Del** button to delete one character.
By pushing **Back** button, you can reach the previous screen (**Main menu screen**).

- **CLINICAL SCREEN 2: ENTER DONOR/PERFUSION ID**



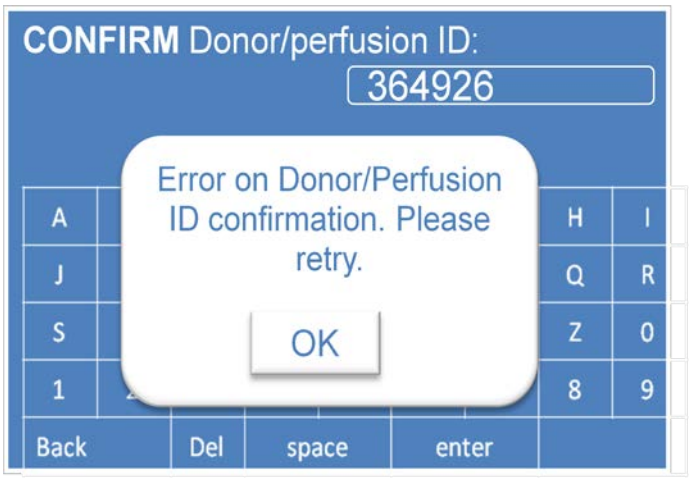
This screen is displayed after pressing **Enter** button on the keypad on the **Clinical screen 1: User name.**
Please add the Donor / Perfusion ID to the trend record using the keypad and press **Enter** to validate and go to the next step.
You can delete characters by pushing on the **Del** button to delete one character.
By pushing **Back** button, you can reach the previous screen: **Clinical screen 1: User name**.

- **CLINICAL SCREEN 3A: CONFIRM DONOR/PERFUSION ID**



This screen is displayed after pressing the **Enter** button on the keypad on the **Clinical screen 2: Enter Donor/Perfusion ID.**
Please confirm the Donor/Perfusion ID and press **Enter** button.
You can delete characters by pushing on the **Del** button to delete one character.
By pushing **Back** button, you can reach the previous screen: (**Clinical screen 2: Enter Donor/Perfusion ID**).

- **CLINICAL SCREEN 3B: ERROR CONFIRMATION DONOR/PERFUSION ID**

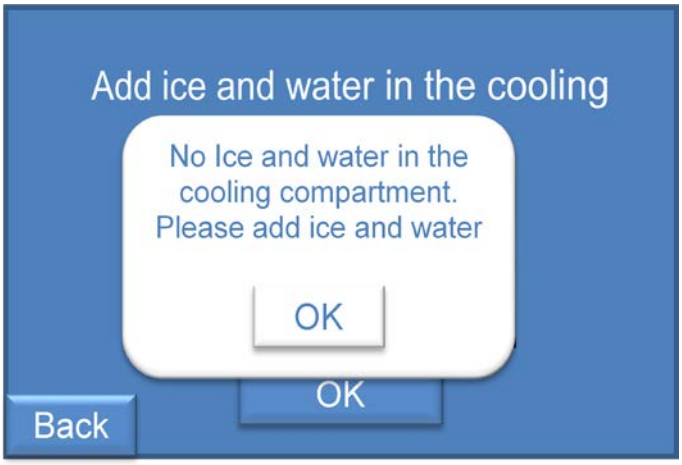


If your confirmation of the Donor/ Perfusion ID doesn't match, this message box is displayed. Please push **OK** button to go back to the **Clinical screen 2: Enter Donor/Perfusion ID,** and enter and confirm the **Donor/perfusion ID.**

- **CLINICAL SCREEN 4A: ADD ICE AND WATER**

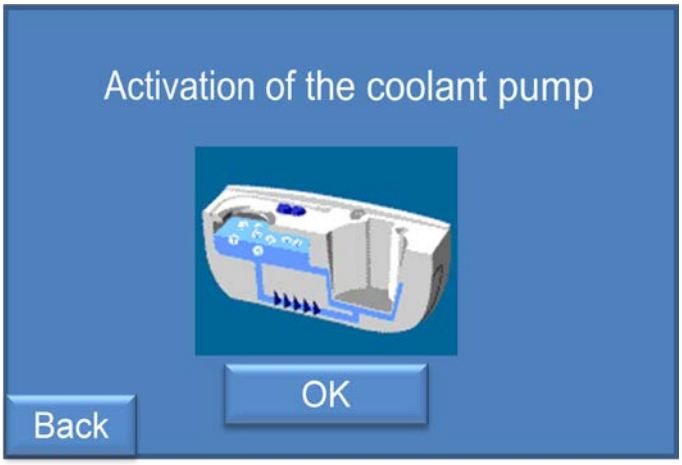
This screen is displayed when the user presses the **Enter** button on the keypad on the **Clinical screen 3a: Confirm Donor/Perfusion ID.**
Fill the ice compartment fully and add ½ to 1 liter cold water and press **OK** to confirm.
The ice and water permit the regulation of the perfusate temperature in the cassette.
By pushing the **Back** button, you can reach the previous screen (**Clinical screen 3a: Confirm Donor/Perfusion ID).**

- **CLINICAL SCREEN 4B: NO ICE AND WATER**



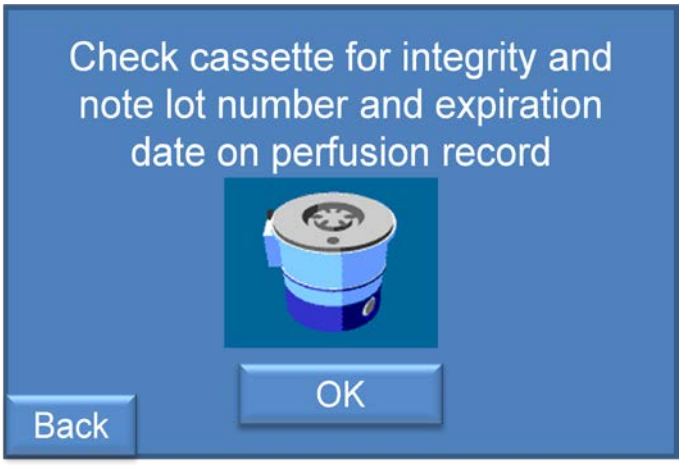
The Waves control unit has a level sensor in the ice compartment. If the minimum level of water is not detected before your press **OK** button on the **Clinical screen 4a: add Ice and water**, this message box appears.
Please press **OK** to go back to the **Clinical screen 4a: add ice and water,** and add ice and water in the ice compartment.

- **CLINICAL SCREEN 5: ACTIVATE COOLANT PUMP**



This screen is displayed when you press the **OK** button on the keypad on the **Clinical screen 4a: Add ice and water.** An animated graphic of a pump operating is shown.
Please push **OK** to activate the coolant pump and go to the next step.
During perfusion, the coolant pump is activated when the temperature is 0.5 degree Celsius higher than the temperature set in the Technical Menu (user defined but usually 5°C), and deactivated when the temperature is lower than 4.5 °C. The aim is to keep the temperature in the cassette at Perfusion Temperature +/-0.5°C. (5°C +/- 0.5°C).
By pushing Back, you can reach the previous screen **Clinical screen 4a: Add ice and water.**

- **CLINICAL SCREEN 6: CHECK CASSETTE**

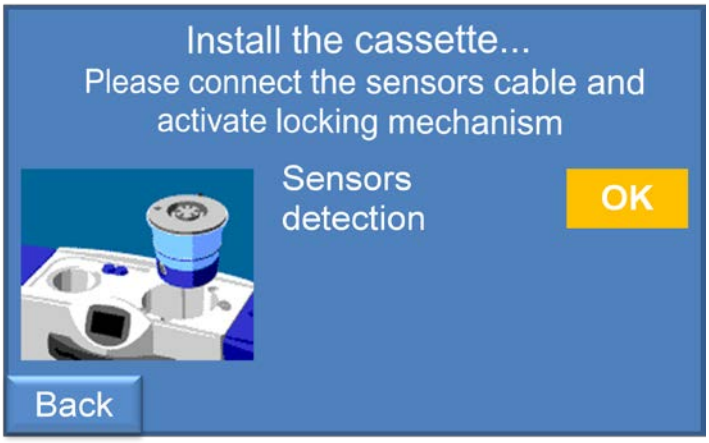


This screen is displayed when you press the **OK** button on the **Clinical screen 5: Activate coolant pump**.
Please check the cassette expiration date, cassette integrity and note the lot number and expiration date on the perfusion record.

If you detect a problem, you must change the cassette, communicate the defect to the WMS technical support, and return the damaged cassette.

If no problem is detected, please press **OK** to validate and reach the next step**.**
By pushing the **Back** button you can go to the previous screen (**Clinical screen 5: Activate coolant pump**).

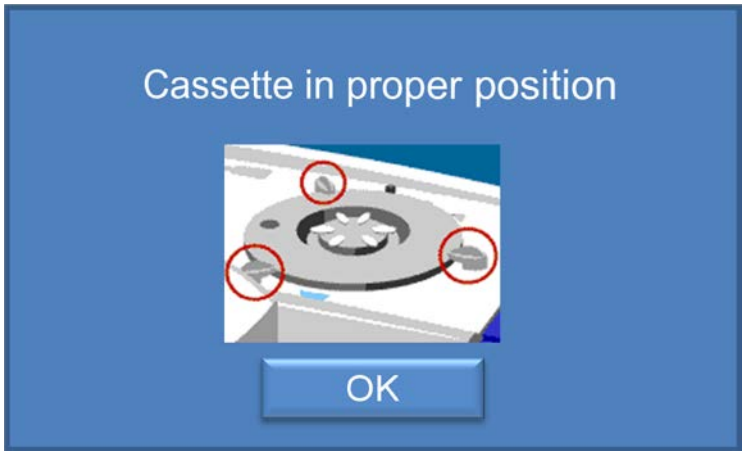
- **CLINICAL SCREEN 7: INSTALL CASSETTE**



This screen is displayed when you press the **OK** button on the **Clinical screen 6: Check Cassette**.
With gloved hands holding the side of the cassette, but not touching the lid of the cassette, install the cassette in its compartment, connect the sensor cable, and activate the 3 locking mechanisms. Do not touch the top of the cassette lid during this process.

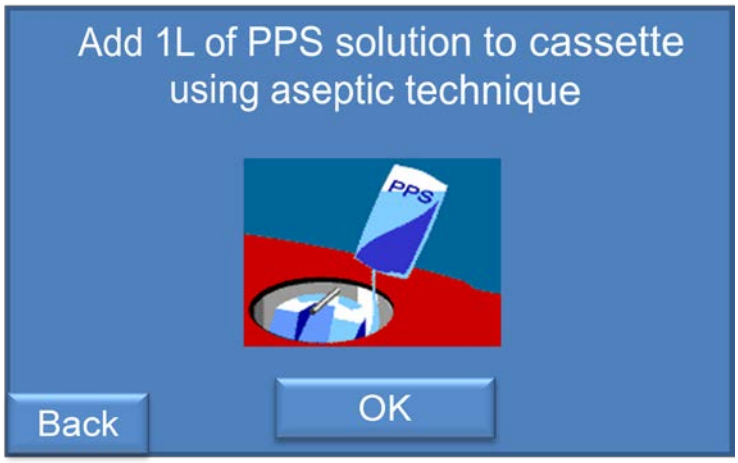
The device automatically detects the two sensors in the cassette (pressure and temperature).
The device has to detect both the pressure and the temperature sensor to be able to go to the next step. If one or several sensors are not detected, the system stays at this step and the perfusion cannot be done. In this case, please check the connection of the cables or call WMS technical support.
Before the cassette is installed and the sensors detected, a red box is displayed showing the device waiting for the sensor detection.
Installing the cassette properly and connecting the sensor cable makes the corresponding red box become **yellow** with an **OK** message displayed.
The WAVES control unit goes automatically to the next steps if the sensors are detected.
Pushing the **Back** button, you can go to the previous screen (**Clinical screen 6: Check Cassette**)

- **CLINICAL SCREEN 8: CASSETTE IN PROPER POSITION**



This screen is displayed if the cassette sensors are detected and verified on the C**linical screen 7: Install cassette.**
This screen is displayed for 5 seconds and automatically goes to **Clinical screen 9: place sterile drape.**

- **CLINICAL SCREEN 9: ADD PERFUSATE TO CASSETTE**



This screen is displayed when you press the **OK** button on the **Clinical screen 8: cassette in proper position.**

Add 1 liter of pulsatile perfusion solution into the cassette using aseptic technique and press **OK** button to validate and go to the next step.

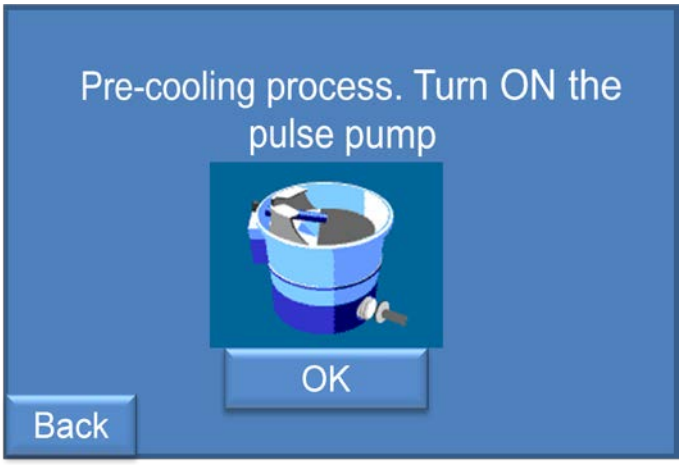
At this point, the space where the device is located can be isolated and the cassette can be allowed to reach temperature (5°C) with the cassette open:

OR

Cassette lids can be aseptically replaced onto the cassette to speed cooling. To further speed the initial cooling process, the outer lids of the device need to be closed to enhance cooling.

Pushing the **Back** button, you can go to the previous screen (**Clinical screen 6: check cassette**.

- **CLINICAL SCREEN 10: TURN ON PULSATILE PUMP**

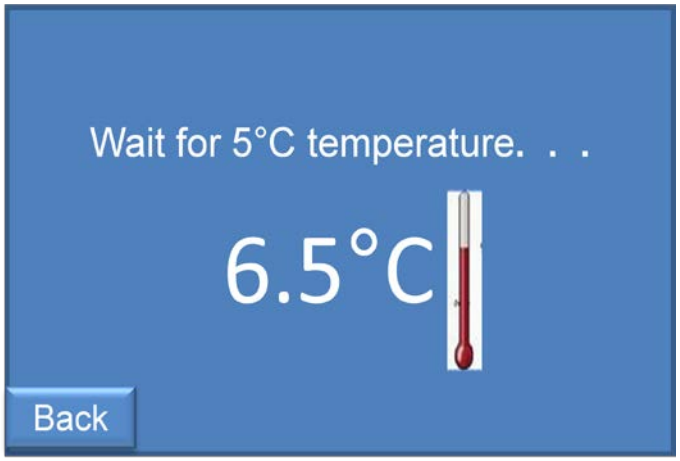


This screen is displayed when you press the **OK** button on the **Clinical screen 9: Add perfusate to cassette.**

Please turn the pulse pump ON by pressing the **OK** button.

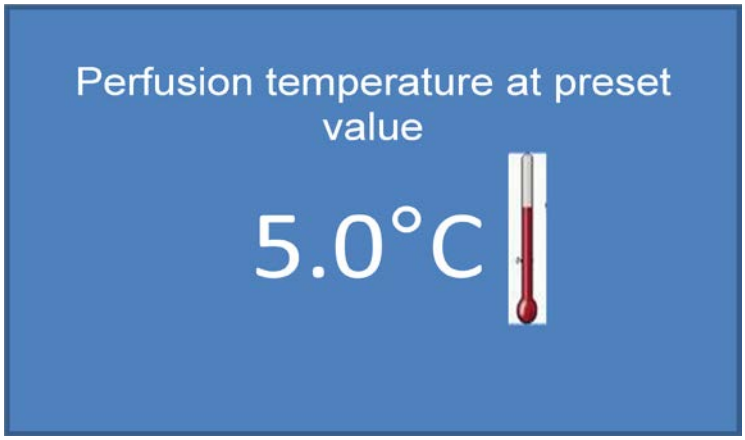
When you push OK, the WAVES control unit engages the pulse pump piston to its “zero” position and the pulsatile pumping begins to prime the cassette and cool the perfusate.
The degree of compression on the below pumphead is set by default.
Pushing OK automatically activates the air pump. The air pump is activated and deactivated every time the pulse pump is activated or deactivated.
By pushing the **Back** button, you can go to the previous screen (**Clinical screen 9: Add perfusate to cassette**).

- **CLINICAL SCREEN 11: WAIT FOR TEMPERATURE**



This screen is displayed when you press the **OK** button on the **Clinical screen 10: Turn On pulsatile pump.**
The current temperature of the perfusate is displayed until it reaches the set perfusion temperature (selected by software and adjusted in the technical menu).
At the same time, the cassette priming is done. The system operates at a high flow rate to accelerate heat exchange.
When the desired temperature is reached, the device automatically goes to the next step (**Clinical screen 12: perfusion temperature at preset value).**
By pushing the **Back** button, you can go to the previous screen (**Clinical screen 10: Turn On pulsatile pump**) and stop both the pulse pump and air pump.

- **CLINICAL SCREEN 12: TEMPERATURE AT PRESET VALUE**



This screen is displayed when preset temperature is reached on the **Clinical screen 11: wait for temperature**.
At this step, the target flow rate is decreased to a medium value (set in technical menu). This screen is displayed during 5 seconds and the system automatically goes to the next steps (**Clinical screen 13: place kidney).**

As a safety measure, you cannot move forward in the perfusion process until the temperature is reached.

- **CLINICAL SCREEN 13: PLACE STERILE DRAPE**

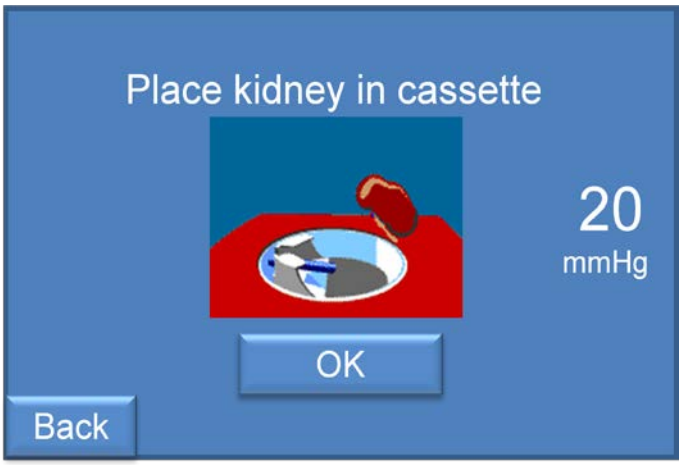
This screen is displayed when you press the **OK** button on the **Clinical screen 12: Temperature at preset value.**

Change into a sterile gown and gloves. Remove the two cassette lids using aseptic technique and place the lids on a sterile surface for later use.

Remove the sterile drape from the packaging and place it on the cassette to protect the device and keep the cassette sterile. The sterile drape should be locked on the cassette.

Push **OK** button using aseptic technique through the sterile drape to validate and go to the next step.
The sterile drape must completely cover the surface of the WAVES including the display and the doors.
Pushing the **Back** button, you can go to the **Clinical screen 10 : Turn On pulsatile pump**.

- **CLINICAL SCREEN 14: PLACE KIDNEY**



This screen is displayed when the preset temperature is reached on the **Clinical screen 13: Place sterile drape**.

IF FIRST STERILE DRAPE WAS REMOVED, FOLLOW DRAPE PLACEMENT PROCESS AS BEFORE MAKING SURE CASSETTE LIDS ARE REMOVED AND STORED ON A CLEAN STERILE SURFACE.

Once, sterile drape is locked in place, follow these instructions to place the kidney on the pump. Aseptically raise the organ tray to the tray rest. Place the kidney on the organ tray in the cassette and connect the artery(s) to a suitable perfusion clamp or cannula. Debubble the artery and clamp/cannula. Finally attach the clam/cannula to the arterial port.

At this step, the WAVES control unit and the pulse pump system operate at a medium flow (set in the technical menu) to protect the kidney from over-pressurization during the connection.

The WAVES automatically provides real-time monitoring of the systolic pressure. The pressure is displayed and set not to exceed a maximum pressure of 20mmHg (preset in the technical menu). The pressure may exceed 20mmHg for a brief time when connecting the kidney but then will reset to 20 mmHg

If the systolic pressure reaches and exceeds the set value, the system decreases the pressure to maintain the pressure at a value lower than or equal to 20mmHg (set in the technical menu).

Pressing **OK** button to validate and go to the next step.
By pushing the **Back** button you can go to the **Clinical screen 13: Place sterile drape**.
This action stops both the pulse pump and air pump.

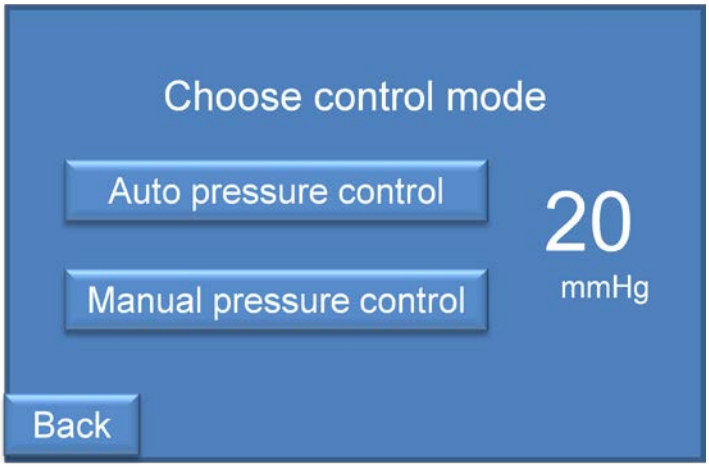
- **CLINICAL SCREEN 15: SET PERFUSION PRESSURE**

This screen is displayed when you push the **OK** button on the **Clinical screen 14: place kidney.**

Please set the desired systolic perfusion pressure the device will be expected to reach during the perfusion and press OK to go to the next step. You can increase or decrease the systolic pressure at which the device will initially operate by using the up and down arrow.

Maintaining pressure on the arrows automatically changes the value of pressure.
By pushing the **Back** button you can go to the previous screen (**Clinical screen 14: place kidney)**.

- **CLINICAL SCREEN 16: PRESSURE CONTROL MODE**



This screen is displayed when you push OK on the **Clinical screen 15: set perfusion pressure.**

Select the pressure control mode by pushing Auto pressure control or Manual pressure control. A real time pressure is displayed on this screen.

- **Auto pressure control:**

In AUTO control mode, the set pressure is constantly maintained and regulated. The compression on the bellows pumphead will be increased or decreased to maintain the pressure. In this mode, 2 minutes of constant pressure at 20 mmHg (the initial pressure selected in the technical menu) is respected. Then the pressure will increase by 5 mmHg every 2 minutes (as set in the technical menu) until the desired perfusion pressure is reached (set on the previous screen).

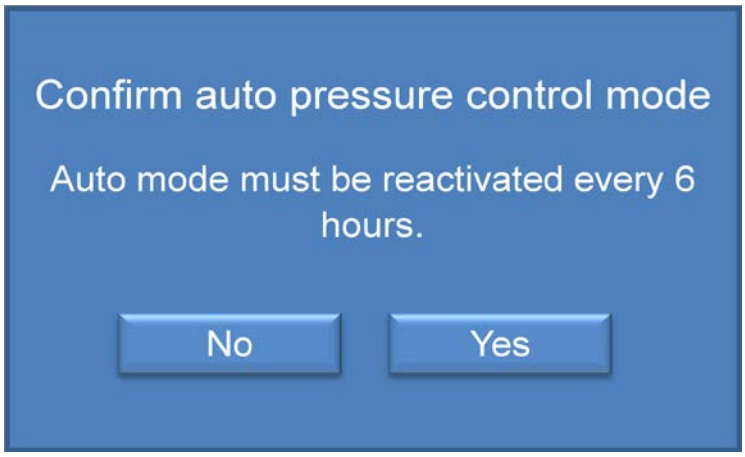
- **Manual pressure control:**

In MANUAL control mode, you can increase or decrease the systolic pressure as desired. ***The pressure is not auto-regulated.*** In this mode, the user will choose the time to reach the perfusion pressure. The time to reach the manually selected pressure is only applied the first time the system has to reach the set pressure selected at **Clinical screen 15: set perfusion pressure.** After that, if the user changes the set pressure, the pressure will be reached instantaneously.

Pushing **Auto pressure control** button goes to the **Clinical screen 17a: Confirm auto pressure control mode.**
Pushing **Manual pressure control** button goes to the **Clinical screen 17b: Confirm Manual pressure control mode.**

By pushing the **Back** button, you can go to the previous screen (**Clinical screen 15: set perfusion pressure).**

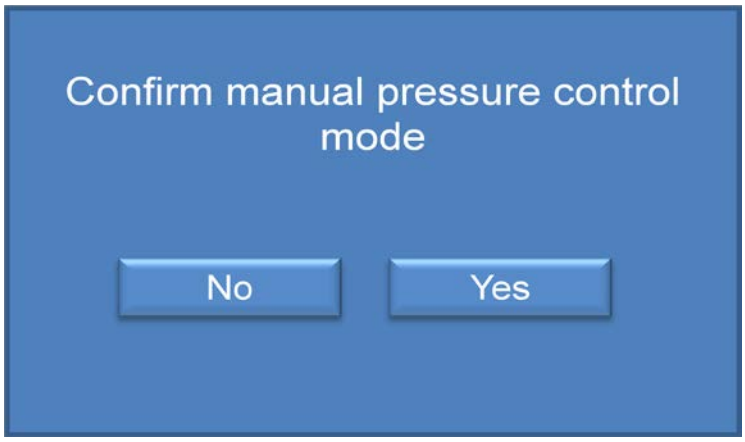
- **CLINICAL SCREEN 17A: CONFIRM AUTO PRESSURE CONTROL MODE**



This screen is displayed when you push the **Auto pressure control** button on the **Clinical screen 16: Pressure control mode.**
Please press YES to confirm your choice or NO to cancel it and go back to the previous step (**Clinical screen 16: Pressure control mode).**

The Auto Pressure Mode is only activated for a maximum of 6 hours and then must be reactivated, to protect the kidney. After 6 hours, the manual mode is activated. If the user wants to stay in auto mode he has to reactivate the auto mode.

- **<u>CLINICAL SCREEN 17B: CONFIRM MANUAL PRESSURE CONTROL MODE</u>**



This screen is displayed when you push the **manual pressure control** button on the **Clinical screen 16: Pressure control mode.**
Please press YES to confirm your choice or NO to cancel it and go back to the previous step (**Clinical screen 16: Pressure control mode).**

- **CLINICAL SCREEN 17C: TIME TO REACH PERFUSION PRESSURE**

This screen is displayed when you push the **Yes** button on the **Clinical screen 17b: Confirm Manual pressure control mode.**
Please set the desired time you want the system to take to reach the perfusion pressure set on **Clinical screen 15: set perfusion pressure**, by pressing the UP or Down arrow.
This control mechanism is only used for the first increase of pressure at the beginning of the perfusion.
Then, please press the **OK** button to validate your setting and goes to the next step (**Clinical screen 18: starting perfusion).**

- **CLINICAL SCREEN 18: STARTING PERFUSION**

This screen is displayed when you push either:

- The **Yes** button on the **Clinical screen 17a: Confirm Auto pressure control mode.**
- The **OK** button on **Clinical screen 17c: Time to reach perfusion.**

This screen is only displayed for 5 seconds to inform you that perfusion will begin. After 5 seconds, the WAVES control unit goes to the next steps and begins to regulate the pressure at the set perfusion pressure value.

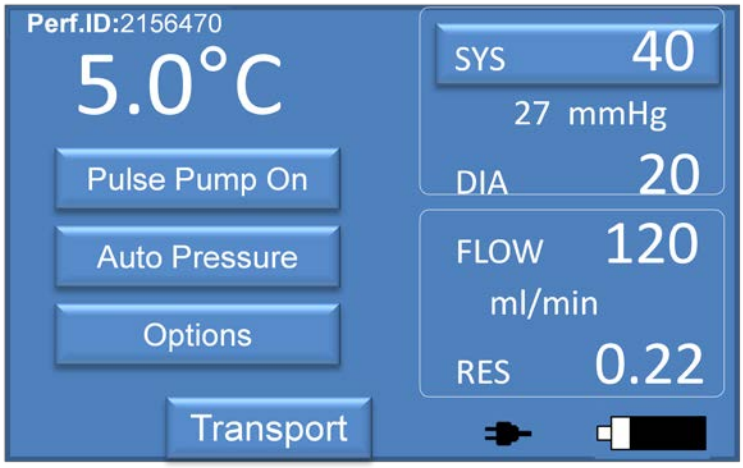
At this point the perfusionist should check for leaks and if none are found, then apply the webbed membrane over the kidney to control (limit) kidney movement on the platform.

The platform should be lowered into the solution.

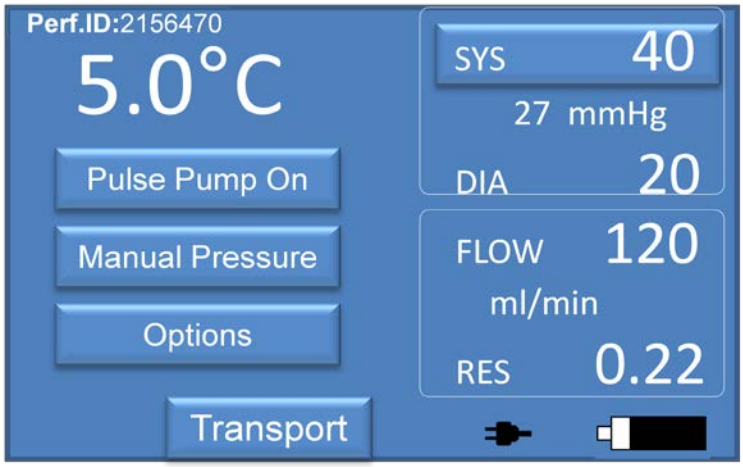
The drape should be removed and the lids aseptically placed on the cassette and locked.

Finally, the cassette should be labeled as described in your protocol.

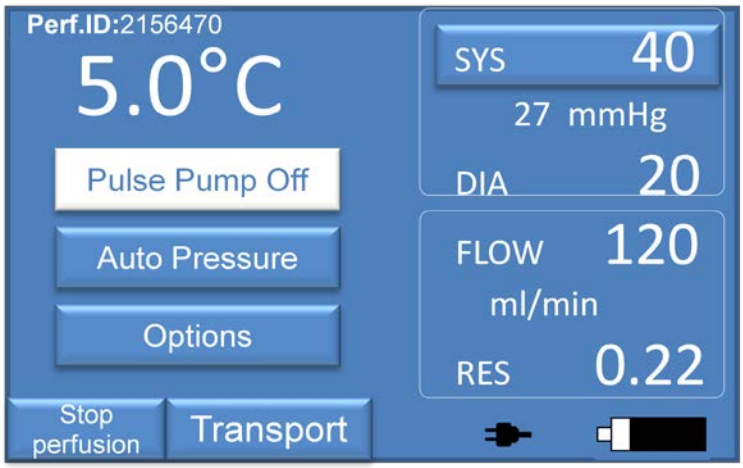
CLINICAL SCREEN 19: MAIN PERFUSION WINDOW



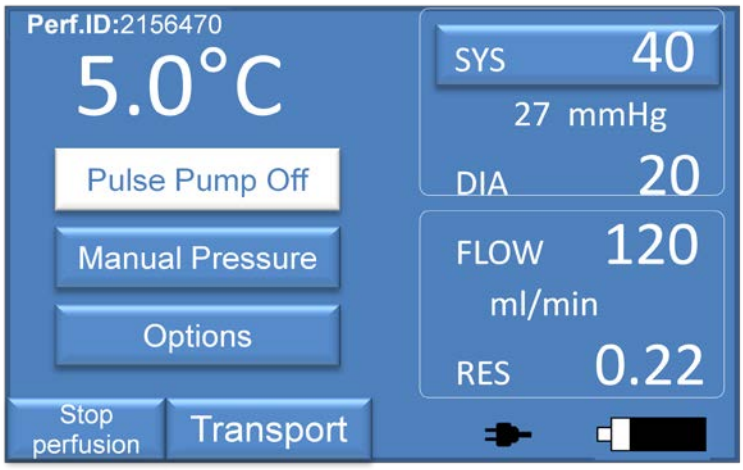
Auto pressure mode / Pulse pump ON/touchpad unlock/no alarms



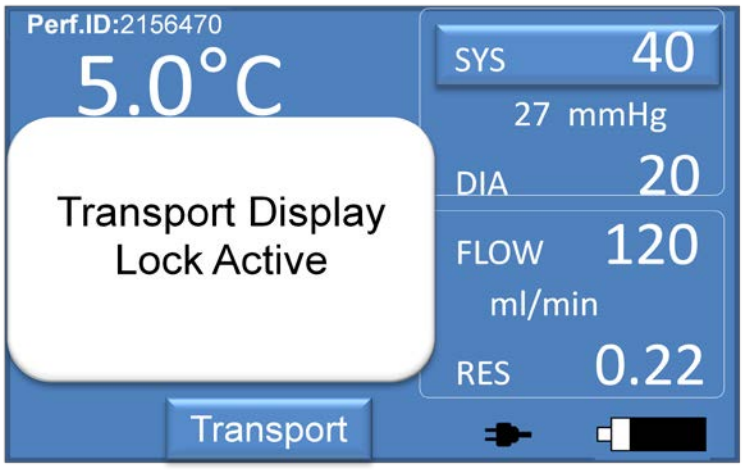
Manual pressure mode / Pulse pump ON/touchpad unlock/no alarms/AC Main connected



Auto pressure mode / Pulse pump Off/touchpad unlock/no alarms/AC Main connected



Manual pressure mode / Pulse pump Off/touchpad unlock/no alarms/AC Main connected



Auto pressure mode / Pulse pump On/touchpad locked/no alarms/AC Main connected

This screen is displayed after all the preliminary steps are completed and is the main perfusion screen.

Different information and control are displayed:

- ***Perfusion ID : EXAMPLE: 2156470***: Perfusion ID entered at the beginning of the perfusion steps.
- ***5°C***: Temperature of the perfusate.
- ***Pulse pump ON*** or ***Pulse pump OFF***: State of the pulse pump. You can turn On or OFF the pulse and the air pump by pushing on this control. This allows additional work to be performed in the cassette without perfusion continuing.
- ***Auto pressure*** or ***Manual pressure:*** activated pressure regulation mode (Auto or Manual). You can display the pressure regulation mode message box to change the mode by pushing on this control.
- ***Options:*** to have access to the Options Menu.

- ***SYS + value:*** permit to see the actual systolic value (in mmHg) and change this value by pushing on the button. Press on the control permit to have access to the pressure setting message box.
- ***value +mmHg:*** display of the Mean pressure value. Mean pressure is calculated using the formula (Sys+2Dia)/3.
- ***DIA + value:*** display of the diastolic value.
- ***Flow + value mL/min*** : display of the perfusate flow
- ***Res + value:*** display of the renal resistance value. Renal resistance is calculated by mean pressure (mmHg)/ flow (ml/min).

On the bottom of the screen, different controls and information are also available:

- ***Stop perfusion:*** Only displayed when the pulse pump is OFF. This command permits to end the perfusion and goes back to the Main Menu screen.
- : Battery symbol which permits to have a global view of the remaining charge of the batteries. You can also push on this symbol to display a message box showing the percentage of charging of each battery and the estimated hours remaining.
- **Transport** button : you can lock and unlock the touchpad screen by pushing on this button
- *After 60 seconds, if no one touches the display, the touchpad is automatically locked. To unlock the touchpad you can touch any area of the screen to display a message box to confirm your choice.*
- When the AC line is plugged into a proper socket, a symbol appears on the screen to alert the user the Main is plugged.

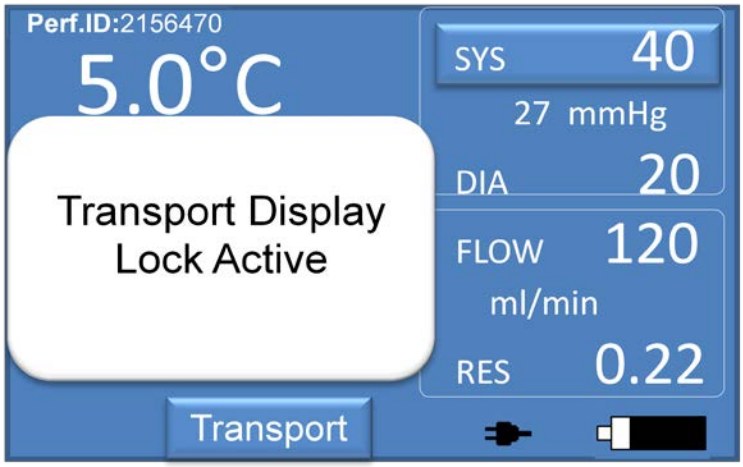
- **CLINICAL SCREEN 20: CONFIRMATION MESSAGE BOX**

  - *Change pressure control confirmation*

This message box is displayed when you want to change the pressure regulation control mode on the display panel, if you push on the **Auto Press** or **Manual Press** button.
After 6 hours of perfusion in auto pressure control mode, the manual mode is automatically activated.
Please press **Auto** to activate the Auto pressure regulation mode or **Manual** to activate the Manual pressure regulation mode.

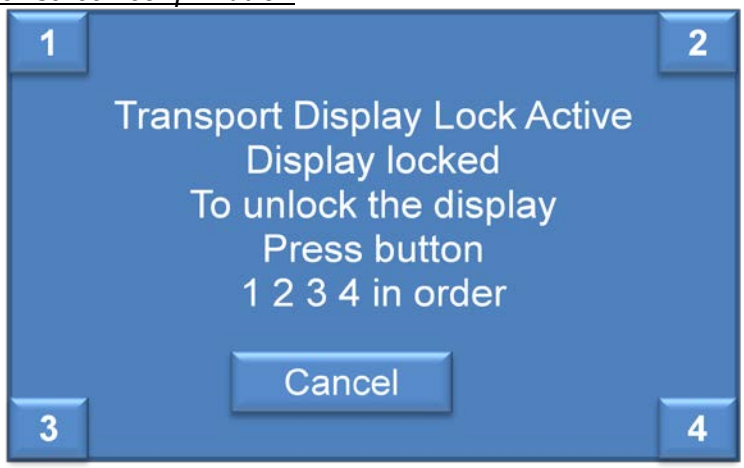
- *Lock screen confirmation*

This message box is displayed if you want to lock the screen touchpad during a transport by pushing on the **Transport** button during a perfusion:
Please press on **Yes** if you want to confirm your choice and lock the screen or **No** you want to cancel your choice and keep the screen unlocked.

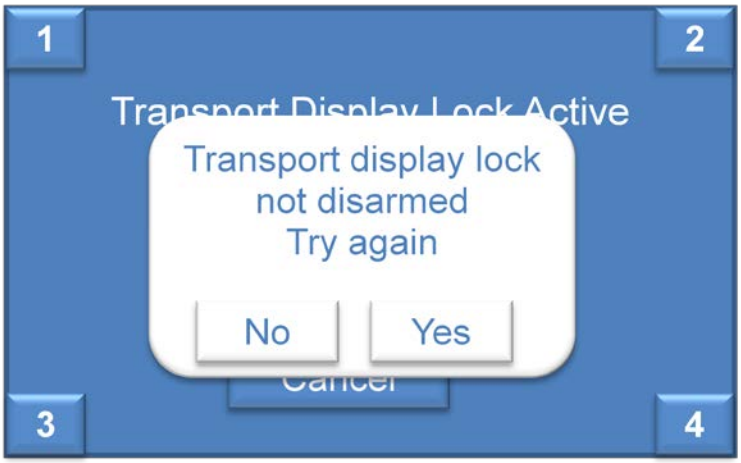


This screen appears once the display is locked. To unlock the display, push on any area of the screen to display the unlocking confirmation message.

- *Unlock screen confirmation*

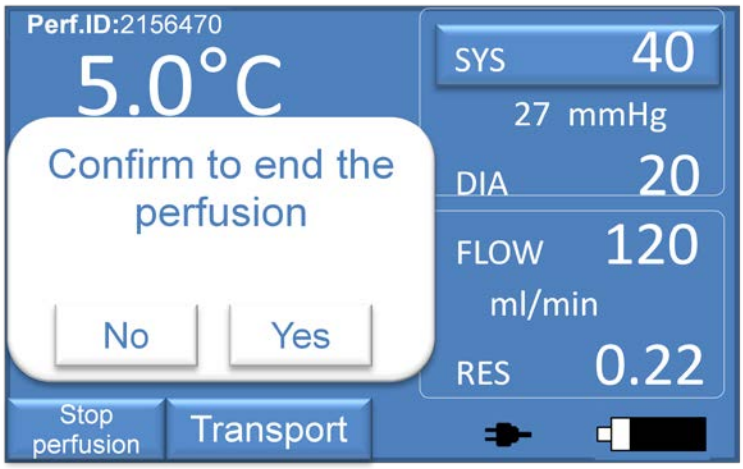


This message box is displayed if you touch the screen touchpad when the screen is already locked.
Please press in the correct order the button 1, 2, 3, 4 to unlock the screen.
Press cancel to keep the screen locked.



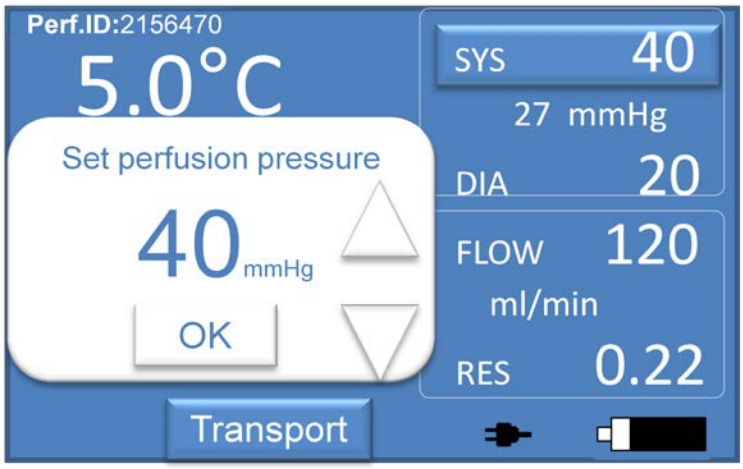
This message appears if the 1, 2,3,4 buttons are not selected in the correct order or if you didn't push on these buttons.
Press yes to try again or no to cancel and keep the screen locked.

- *End perfusion confirmation*



This message box is displayed if you push the **STOP PERFUSION** button on the Main perfusion screen. This button is active (and displayed on the screen) only if the pulse pump is turned off. Please press **YES** to confirm your choice and end the perfusion. Be careful, this action is definitive. The perfusion data will be closed and saved in the history and the perfusion ended.
Please press **NO** to cancel your choice and keep the perfusion active.

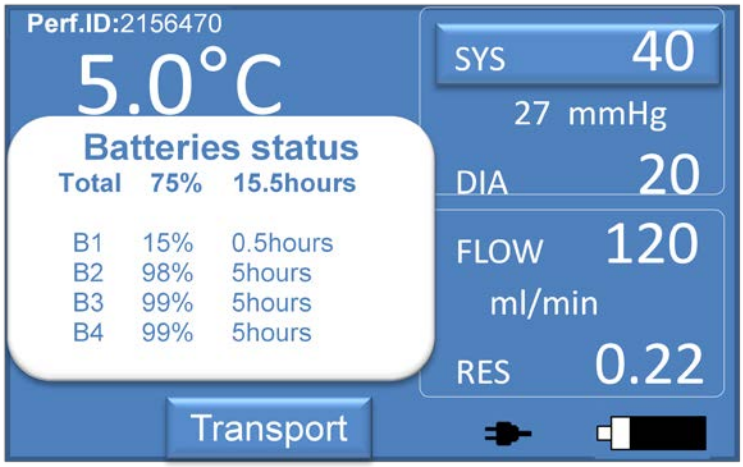
- **CLINICAL SCREEN 21: CHANGE PERFUSION PRESSURE MESSAGE BOX**



This message box is displayed when you push on the SYS button during a perfusion.
Please change the systolic perfusion pressure you want the system to perform.

Using the up or down arrow, you can increase or decrease the set pressure value.
Press **OK** button to confirm your choice.
In the Manual pressure regulation mode, the pressure is instantaneously reached.
In the Auto pressure regulation mode, the pressure is increased or decreased gradually (5mmHg every 2 minutes set in technical menu by default) until the set pressure is reached.

- **CLINICAL SCREEN 22: BATTERIES STATUS MESSAGE BOX**

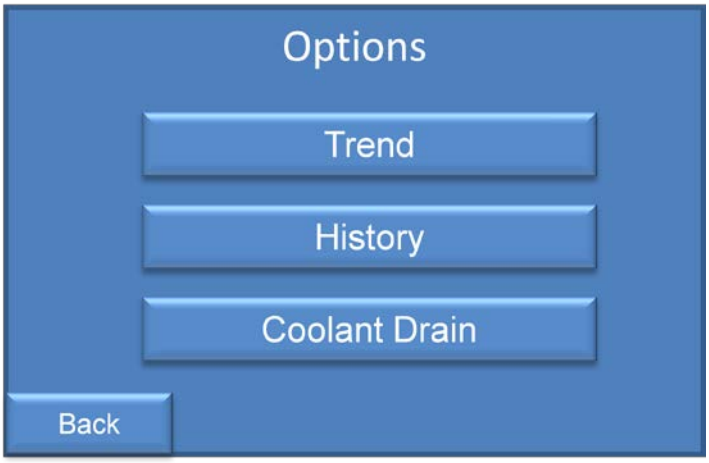


This screen is displayed if you push the battery symbol during a perfusion.
You can see the state of each battery:

- Percentage of charge of each battery and
- Number of hours remaining for each battery.

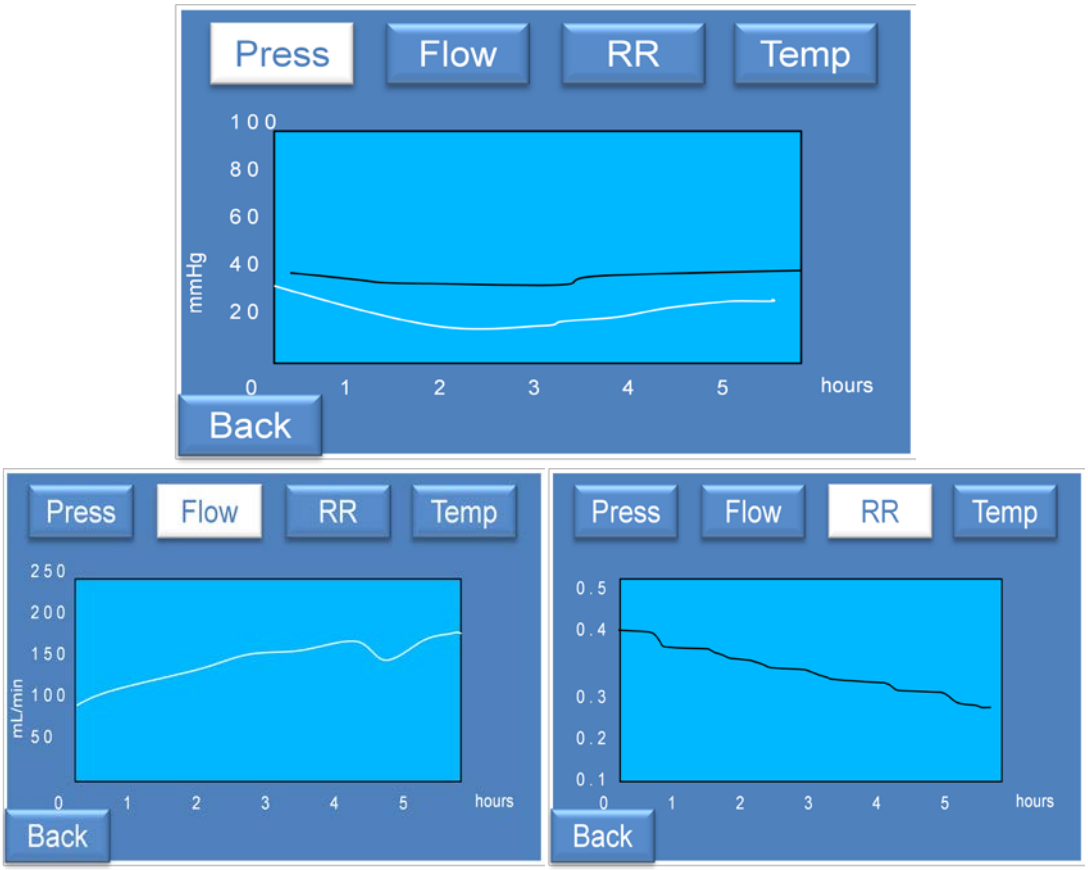
A global percentage of charge and number of hours remaining is also available.
This message box is displayed for 5 seconds and disappears.

- **OPTION SCREEN**



This screen is displayed when you push on the Options button on the Main Perfusion screen during a perfusion.
Pushing the **Trend** button, you can have access to different trends for the current perfusion (systolic, diastolic, flow, renal resistance): See **Trend screen**.
Pushing the **History** button, you can have access to the previous perfusion data (stored in the memory): See **Perfusion history screen**.
Pushing the **Drain** button, you can drain the ice compartment: See **Coolant drain screen.** This control permits to drain the water and replace the ice in the ice compartment during a perfusion.
By pushing **Back** you can go to the previous step (Main Perfusion screen).

- **TREND SCREENS**

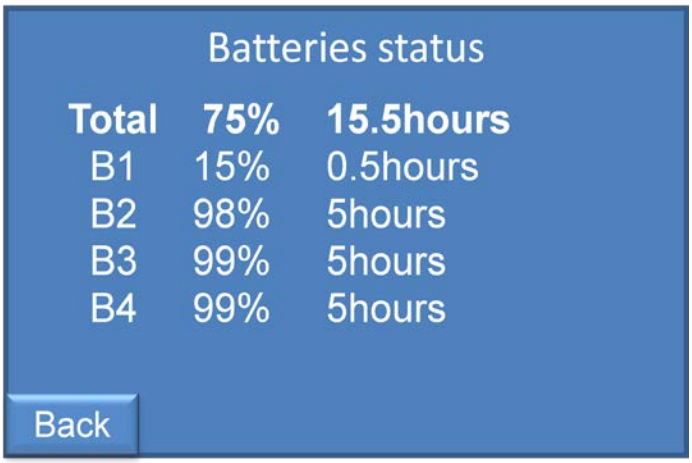


This screen appears when you push on the **Trend** button on the Options screen.
On this screen, you can have access to 4 different Trends:

- Pressure trends (Systolic and diastolic).
- Flow trend.
- Renal resistance trend.
- Perfusate temperature trend.

You can switch between the different Trend by pushing on the corresponding button (Press, Flow, RR, Temp).
The Control button of the activated trend is displayed in white. The others are in blue.

- **BATTERY STATUS SCREEN**



You can have access to the battery status by pushing on the **Battery Status** button on the main Menu Screen.

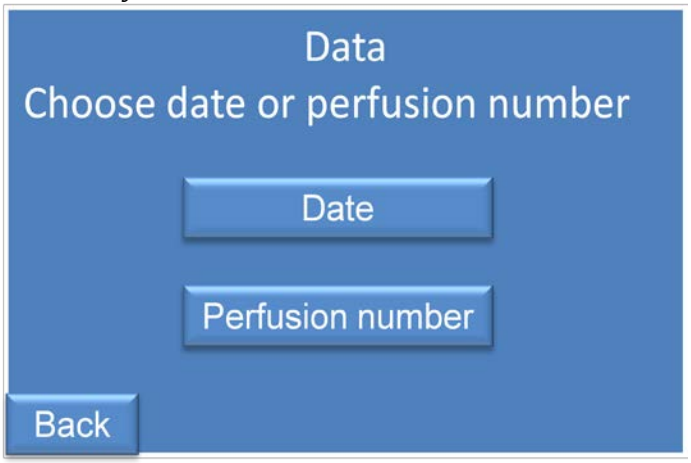
- Percentage of charge of each battery and
- The number of hours remaining for each battery.

A global percentage of charge and number of hours remaining is also available.
Pushing the **Back** button, you can go to the main menu screen.

- **PERFUSION HISTORY SCREENS**

The following screen details the different steps to have access to the data history files.

- *Perfusion History Menu screen*



This screen appears when you push the **History** button on one of the following screens:

- **Options screen**
- **Main Menu screen**

You have access to the previous perfusion data and can make your selection by date or by perfusion number.
Please push the **Date** button if you want to select the files by date**.**
Please push the **Perfusion number** button if you want to select the files by perfusion number.
Pushing the **Back** button, you can go to the previous screen.

- *Perfusion history screen :data selection*

One of these screens appears when the user pushes the Date or the Perfusion Number on the Perfusion History menu screen
Please select the perfusion files you want to access by using the down and up arrows and push the **OK** button to validate your choice. Two stars (**) appear in front of the selected data.

Pushing the **Back** button, you can go to the previous screen.

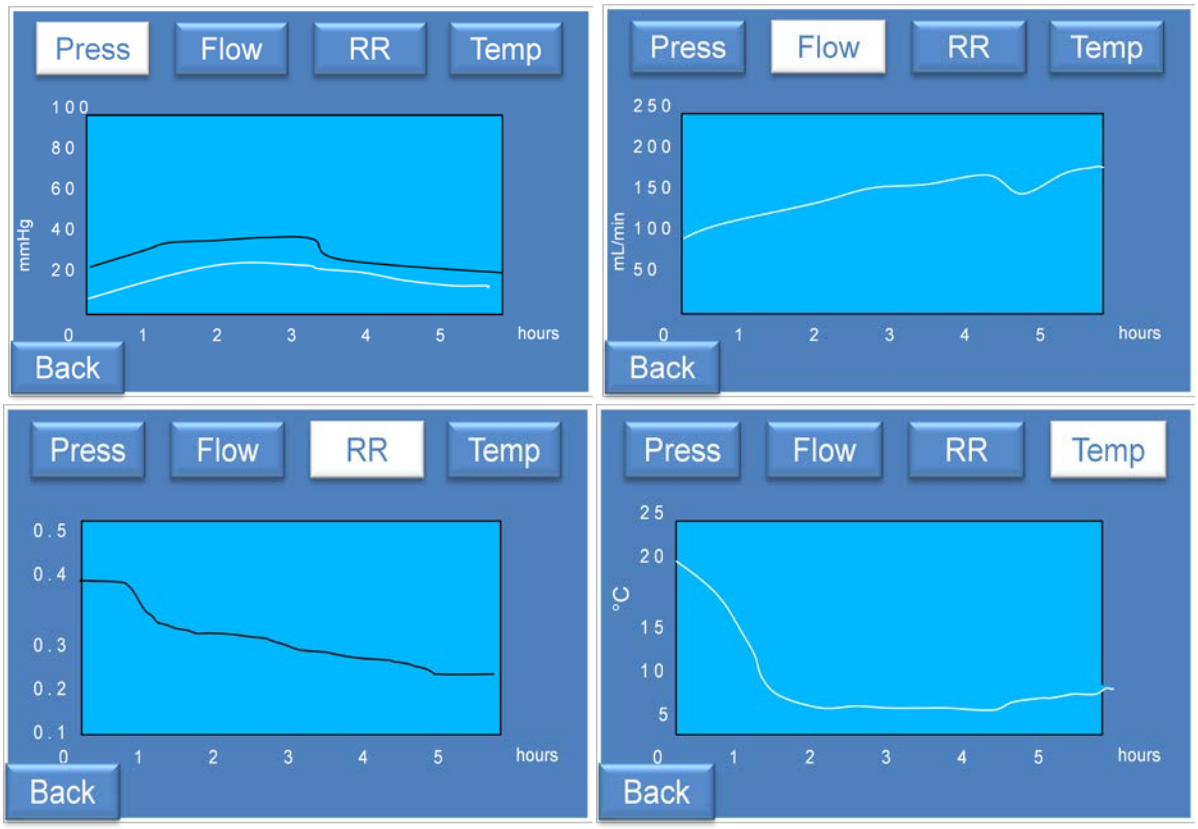
- Perfusion History screen : data table

The selected perfusion files are displayed as shown. A table gives you all the systolic and diastolic pressures, the flow, the perfusate temperature and the renal resistance values for the perfusion case. You can consult the data by using the up and down arrows.
This screen displays also the beginning date and time of the perfusion and the perfusion number.
Pushing the **Chart** button, you can see the data in a graphic format: see **Perfusion History screen: data chart**.

Pushing the **Transfer** button, you can transfer the data using a USB flash drive in comma separate value (.CSV) format. The USB flash drive is automatically detected by the WAVES control unit.

Pushing the **Back,** you can go to the previous step.

- Perfusion History screen : data chart



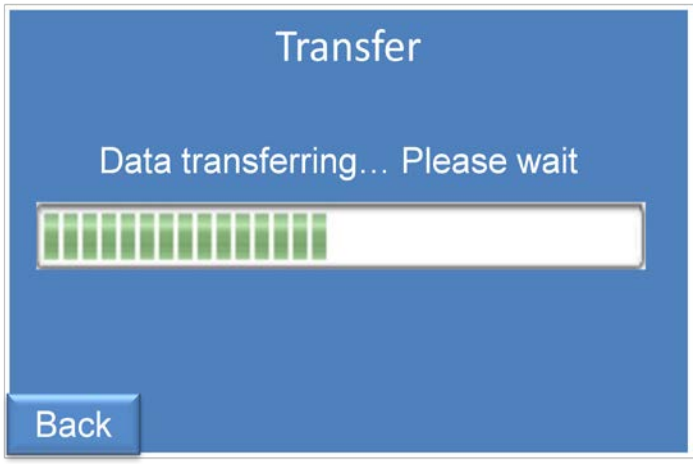
This screen appears when you push on the **Chart** button on the previous step (*Perfusion History screen: data table*).
On this screen, you can have access to 4 different Trends:

- Pressure trends (Systolic and diastolic).
- Flow trend.
- Rena résistance trend.
- Perfusate temperature trend.

You can switch between the different Trends by pushing on the corresponding button (Press, Flow, RR, Temp).
The Control button of the activated trend is displayed in white. The other trend choices are in blue.

Pushing the **Back,** you can go to the previous step.

- Perfusion History screen : data transfer



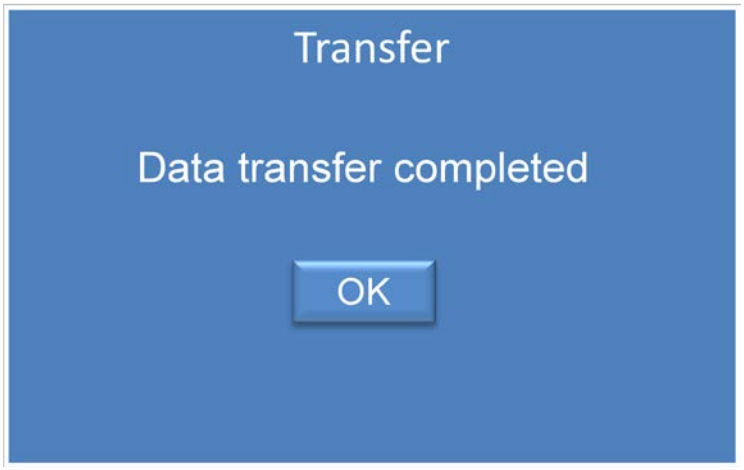
This screen is displayed if you push on the Transfer button on the History screen: data chart or the History screen: data table (if a USB flash drive is connected).

During the transfer, a message **"Data transferring…Please wait**" and the transfer progress bar is displayed to inform the user.

The user will transfer all the data for the perfusion: systolic, diastolic, temp, RR, perfusion number, and date of the beginning of perfusion.

Pushing on the **Back** button, you can cancel the transfer and go to the previous step.

- Perfusion History screen : data transfer completed

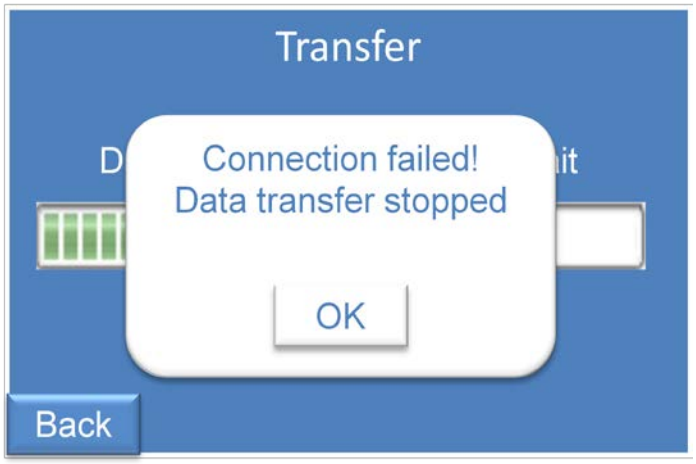


This screen is displayed if the transfer of the perfusion data to the USB flash drive is successful. Please push the **OK** button to validate the transfer and go back to the Main Perfusion screen or to the Main Menu, depending if a perfusion is launched or not.

You can now disconnect the USB flash drive.

To insure proper data transfer, we recommend using a USB flash drive provided as accessory by WMS.

- Perfusion History screen : data transfer failed



This screen is displayed if the transfer failed (disconnection of the USB flash drive or failure during the transfer). The transfer is stopped.

Please push the **OK** button to validate and try again the transfer if needed.

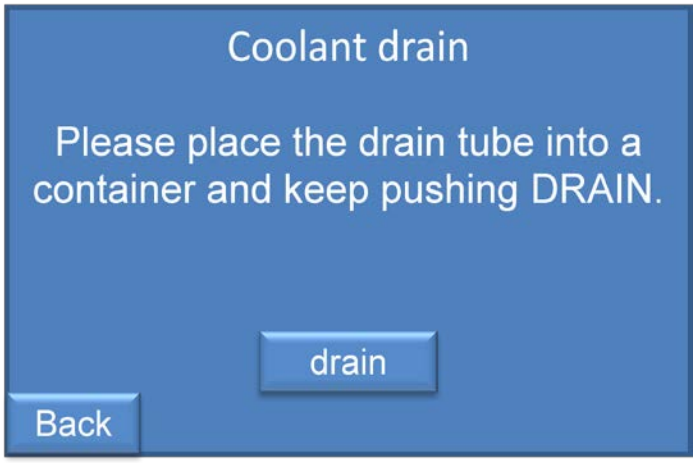
Pushing OK made the system go back to the Perfusion History screen: data table or Perfusion History screen: data chart, depending of the previous state of the system.

- Perfusion History screen : data transfer-USB connection

This screen is displayed if no USB flash drive is detected when you launch a data transfer or the flash drive is not recognized by the WAVES control unit.

Please push the **OK** button, connect a USB flash drive and launch the transfer again.

- **COOLANT DRAIN SCREEN**
    - Coolant drain screen 1



This screen is displayed when you push the **Drain** button on the **Main Menu screen**.

Please place the drain tube outlet in a container and press and hold the **Drain** button.

If you stop pushing the **Drain** button, the draining stops instantaneously.

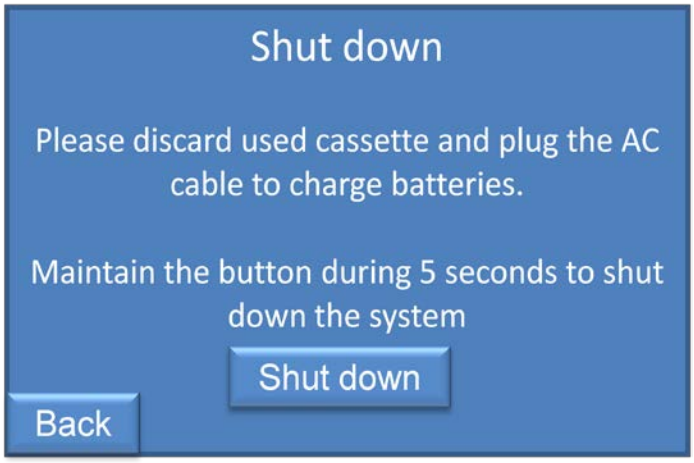
A level sensor in the ice compartment detects the minimal level of water and automatically stops the draining.

When the draining is completed, the system goes to the **Coolant Drain screen 2**.
Pushing the **Back** button, you can go to the previous step (Main Menu screen).

- Coolant drain screen 2

This screen is displayed when the ice/water reservoir is drained completely.
Please push **OK** button to validate the action and go to the **Main Menu screen.**

- **SHUT DOWN SCREEN**
    - Shut down screen 1


Shut down
Please discard used cassette and plug the AC cable to charge batteries.
Maintain the button during 5 seconds to shut down the system
Shut down
Back

This screen is displayed when you push the **Shutdown** button on the **Main Menu screen**.

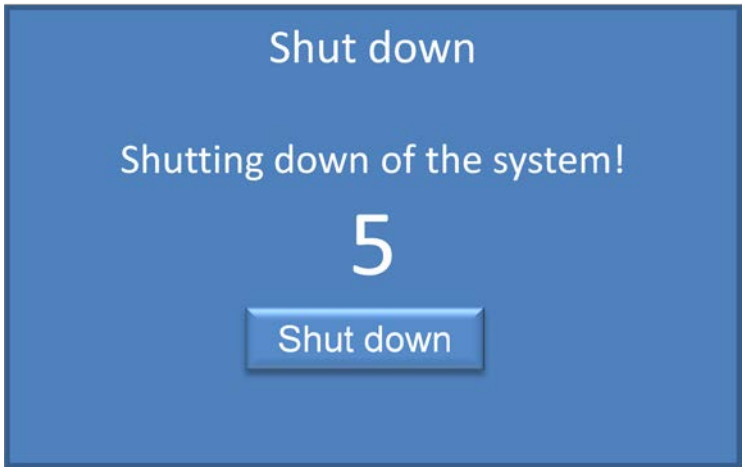
Prior to shut down:

Please remove the cassette, connect the AC cable to charge the batteries and press and hold the **Shutdown** button for 5 seconds.

Maintaining the **Shutdown** button shows the Shutdown screen 2

Pushing **Back** button, you can go to the previous step: Main menu screen.

- Shut down screen 2



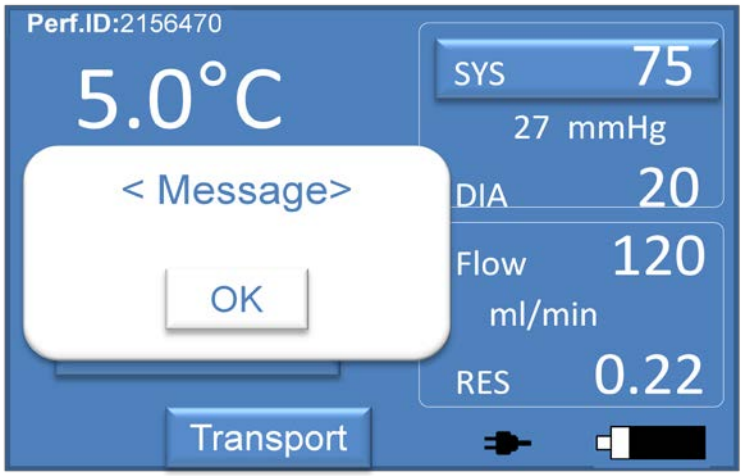
This screen is displayed when you maintain control of the **Shutdown** button on Shut down screen 1.

Please press and hold the **Shutdown** button for 5 seconds to shut down the WAVES control unit.

A counter is displayed on the screen (from 5 to 0) until the system is shut down.

If you stop pushing the Shutdown button, the shutdown system is aborted and the system goes back to the Shutdown screen 1.

- **ALERTS SCREEN**



This screen is displayed when an error / alert occurs.

- **ALARMS SCREEN**

This screen is displayed when an alarm condition occurs.

See also **Alarms and troubleshooting** on page 88.

Each time an alarm occurs, a red message box appears to alert the user and describe the problem.

Depending of the parameters concerned by the alarms:

- The name of the value and value concerned are displayed in red until the problem is identified:
  - Example: The systolic pressure is too high.

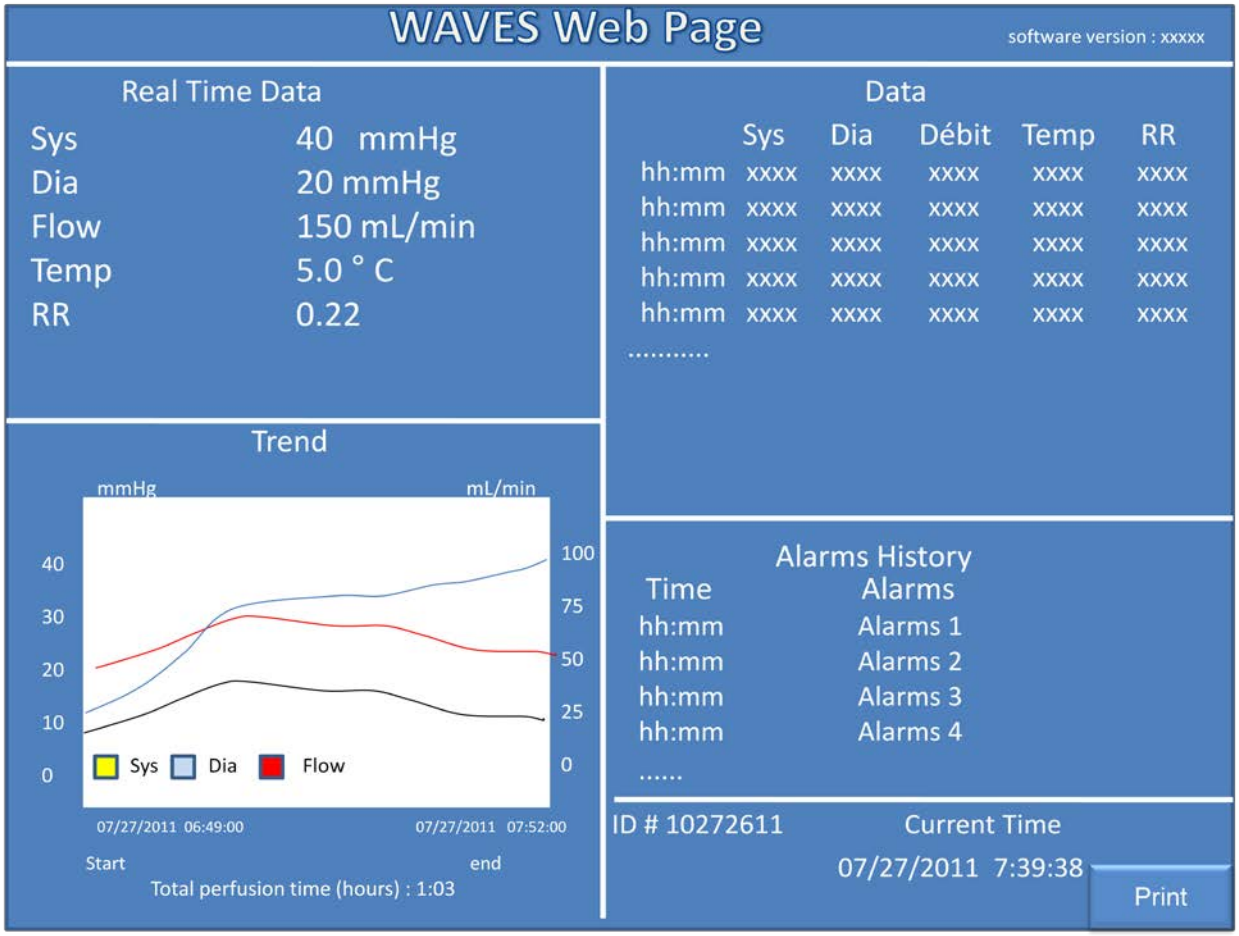
- A red message box is displayed. If you want to hide the message box, please push OK :
  - Example : The systolic is too high

- A sound is activated to alert the user.

  If a new alarm occurs, the sounds are reactivated automatically.

- During an active perfusion, if the system is not in the Main Perfusion screen (Trend screens, history screens, drain screen…) the WAVES control unit goes automatically on the Main Perfusion Screen if any alarm occurs, in order to be able to see the displayed parameters.

WAVES WEBPAGE



The perfusionist can only see the perfusion parameters displayed and print a report consisting of:

- **Real Time Data**: Systolic, diastolic and mean pressures, flow, temperature and renal resistance values, as displayed on the device screen at that time (real time).
- **CURRENT Data:** Systolic, diastolic and mean pressures, flow, temperature and renal resistance values saved in the device for the actual perfusion. The data are displayed from the newest to the oldest. The first data is displayed on the top during the perfusion. The webpage can display up to 15 hours of perfusion data
- **CURRENT Trend:** A chart which represents all data saved in the device for the current perfusion for systolic and diastolic pressures, and flow values.
- **Perfusion Alarms History**: This table lists the alarms that occurred during the perfusion. Up to 16 alarms can be displayed for each case.
- **Perfusion Number**
- **Date and Time at the beginning of this perfusion (allows total perfusion time to be calculated).**

The perfusion webpage can be printed for use in the recipient operating room by clicking on the "Print" button or using the Internet Explorer printing feature.
Per national standards, the perfusion record should be printed and must become a permanent portion of both the donor and recipient medical records.
No change on the perfusion parameters or on the WAVES can be made from the website.

Network connection procedure

- Attach the WAVES to your network using a standard ethernet cable. You may require permission from your IT department.
- Turn ON the WAVES if not done so already.
- On your network attached personal computer, open Waters network scan application FindWaves.exe. Click on the "Refresh" button to look up the IP address for the WAVES. This application can be found on the USB drive provided with the WAVES.
- Using Internet Explorer browser, type the URL: **http://xx.xx.xx.xx/MainFrame.htm.** Replace xx.xx.xx.xx with the IP address obtained in the previous step.
- The WAVES webpage is displayed.

The word **MainFrame.htm** is case sensitive. You may need your IT Administrator to help you add a device to your network. If allowed by your department manager, you can use a wireless router and a simple network setup to wirelessly connect to a laptop or other wireless network capable device.

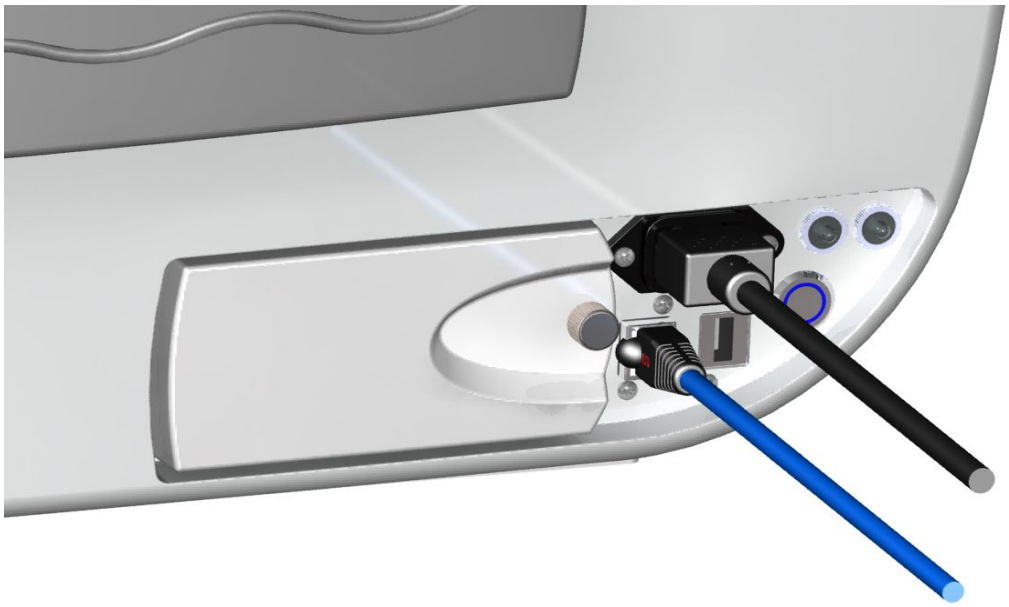


Figure 19: WAVES network connection

ALARMS AND TROUBLESHOOTING

The following table gives a description of the alarms that can occur during the operation of the WAVES system and the associated troubleshooting

Alarm	Condition	Action	Message
No pressure signal detected	• Cassette connector disconnected • Internal controller connection • Broken wires on cassette cables • Broken wires on WAVES cassette interface cable. • Pressure circuitry failure on controller.	WAVES Actions • **Stop pulse pump** • **No value of pressure. The pressure value is replaced by "—"in red.** USER Actions • **Check cassette cable connection** • **Change cassette** • **Call WMS technical support if the problem persists**	**"pressure sensor missing"** **"Cassette missing. Check the cassette."** (if both temperature and pressure sensor are missing)
Systolic pressure Too High	• Kinked tubing • Blocked arteries, arterial lines or kidney • Frozen kidney • Failure of the pressure sensor	WAVES Actions : • **Reset stroke to zero and try to reach again the set pressure** • **The value of systolic pressure is displayed in red.** USER Actions • **Check cassette tubing** • **Check kidney** • **Check cassette cable and sensors** • **Call WMS technical support if the problem persists**	**"systolic pressure too high"**
Systolic pressure Too low	• Leak • Failure of pressure sensor	WAVES Actions : • **The value of systolic pressure is displayed in red.** USER Actions • **Check cassette tubing** • **Check kidney** • **Check cassette cable and sensors**	**"systolic pressure too low"**
Cannot reach set systolic pressure	• Leaks in arterial line • Leaks in bubble trap • Leaks of the arteries. • Failure of the pressure sensor • Failure of the pulse pump	WAVES Actions : • **The value of systolic pressure is displayed in red.** USER Actions • **Check cassette tubing** • **Check kidney** • **Check cassette cable and**	**"unable to reach desired pressure"**

Alarm	Condition	Action	Message
		sensors • **Check cassette** • **Check pulse pump** • **Call WMS technical support if the problem persists**	
No cassette temperature signal detected	• Cassette connector disconnected • Broken wires on cassette cables • Broken wires on WAVES cassette interface cable. • Internal controller connector • Failure of the sensor • Pressure circuitry failure on controller	WAVES Actions : • **Alert the user** • **No value of temperature. The temperature value is replaced by "—" in red**. USER Actions • **Check cassette cable and sensors** • **Call WMS technical support if the problem persists**	**"temperature sensor missing"** **"Cassette missing. Check the cassette."** (if both temperature and pressure sensor are missing)
Cassette temperature Too High (>10°C)	• Failure of the coolant pump • Blocked coolant tubing • Bad contact on heat exchanger • Coolant temperature too high (no ice)	WAVES Actions : • **Alert the user** • **Start coolant pump if ice container temperature is lower than 10°C.** • **Temperature value displayed in RED** USER Actions • **Check cassette cable and sensors** • **Check cassette** • **Change ice** • **Call WMS technical support if the problem persists**	**"Cassette temperature too high"**
Flowmeter not functioning	• Flow controller failure • Connection between flowmeter and controller board	WAVES Actions : • **Replace the value of flow by "—" in RED** USER Actions • **Stop the perfusion and call WMS technical support if the problem persists**	No message
Flow sensor not functioning	• Failure of the flow sensor • Flow sensor disconnected	WAVES Actions : • **Replace the value of flow by "—" in RED** USER Actions **Stop the perfusion and call WMS technical support if the problem persists**	No message

Alarm	Condition	Action	Message
Flow to high	Maximum flow (alarm settings) reached	WAVES Actions : • **Alert the user** • **Display the flow value in RED** USER Actions • **Check cassette tubing (leaking)** • **Check kidney** • **Check flow probe** • **Call WMS technical support if the problem persists**	**"Flow too high"**
Flow too low	Minimum flow (alarms settings) reached	WAVES Actions : • **Alert the user** • **Display the flow value in RED** USER Actions • **Check cassette tubing (kinking)** • **Check kidney** • **Check flow probe** **Call WMS technical support if the problem persists**	**"Flow too low"**
Renal resistance too high	Renal resistance value higher than the maximum limit	WAVES Actions : • **Alert the user** • **Display the RR value in red** USER Actions • **Check cassette tubing** • **Check kidney** • **Check cassette positioning**	No message
Coolant Pump Failure	• Coolant pump trip breaker • Coolant pump current too high. • Damaged coolant pump	WAVES Actions : • **None** USER Actions • **If problems persist, call WMS technical support to change the coolant pump.**	No message
Air pump failure	• No air delivered to cassette	WAVES Actions : • **None** USER Actions **Call WMS technical support to change the air pump**	No message
Battery (1-4) low	• Bad battery • Discharged Battery •	Troubleshoot: WAVES Actions : • **Alert the user** USER Actions • **Check batteries**	**"Battery (1-4) low"**

Alarm	Condition	Action	Message
		• **Check batteries placement** • **Charge batteries** • **If problem persists, call WMS technical support to replace battery (1-4)**	
Battery (1-4) missing	• Battery (1-4) not detected	WAVES Actions : • **Alert the user** USER Actions • **Check batteries placement** • **Install battery**	**"Battery (1-4) missing"**
(no display)	• Turned on power but no display	WAVES Actions : **None** User Actions : • **If problems persist, call WMS technical support to control and/or change the display or the controller**	No message
Touchpad doesn't work	• No response when push on a button	WAVES Actions : **None** User Actions : • **Calibrate touchpad** • **Change the display** • **Control controller board**	No message
Coolant temperature too high	• No ice left • Temperature of the ice container higher than 15°C	WAVES Actions : **Alert the user** User Actions : • **Drain Ice container and replace ice**	**"Ice container temp too high"**
Coolant fluid missing	• Not enough coolant water	WAVES Actions : • **Alert the user** • **Stop coolant pump** User Actions : • **Check ice compartment and add ice and water if necessary.** • **Call WMS technical support if problems persist**	**"No ice and water in the ice container. Please add ice and water"**

WAVES SOFTWARE TECHNICAL MENU: DEFINITIONS AND GENERAL DESCRIPTION

TECHNICAL MENU TABLE OF CONTENTS

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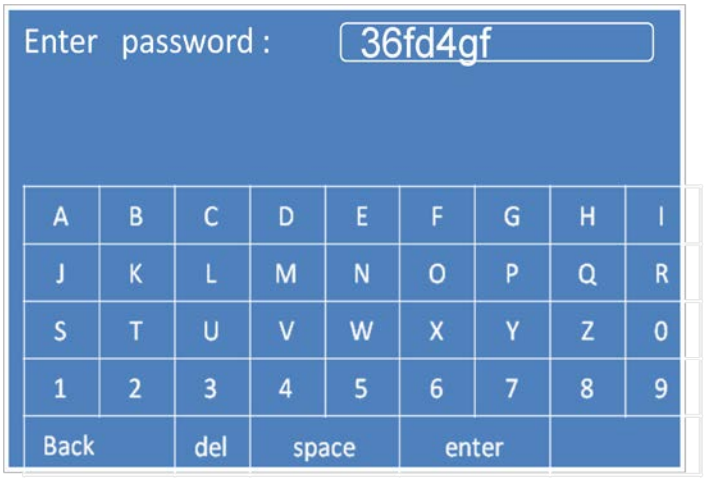
- **Technical Menu screen 1 : Secured connection**



This screen is displayed when you push the Technical Menu button on the Main Menu screen (Software specifications).

The entire Technical Menu is protected by password. Only administrator may access the technical menu. If you lose your password, please call WMS technical support to reset.

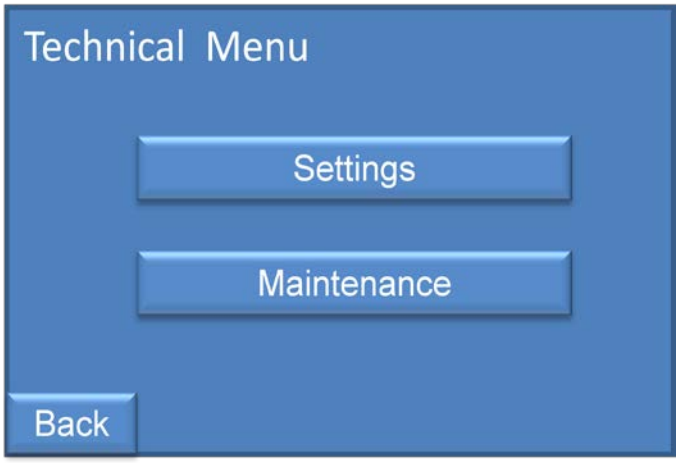
Please enter your password using the keypad and press **Enter** to validate and have access to the Technical Menu screen (if password is correct).

By pushing **Back**, you can go the previous step (Main Menu screen)

- **Technical Menu screen 2 : Wrong password**

If the password is not correct, this message box appears to alert you. Please press **OK** to be able to enter the password again.

- **Technical Menu screen 3 : Menu**



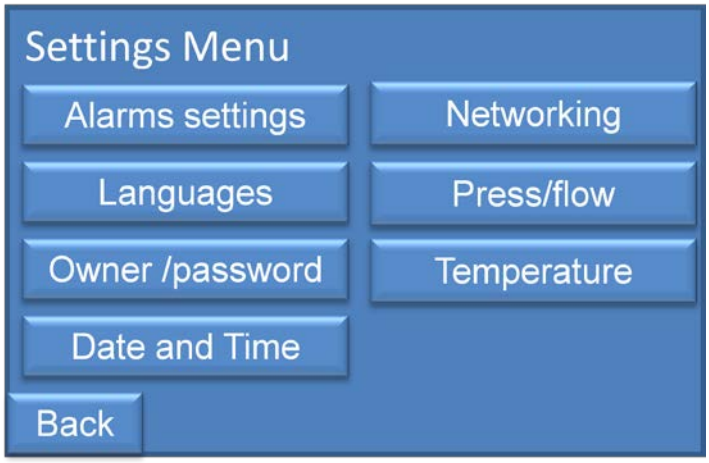
This screen is displayed when the correct password is entered.

Please choose the section you want to access by:

- Pressing **Settings** button to go to the Settings Menu (Technical menu screen 4: Settings Menu).
- Pressing **Maintenance** button to go to the Maintenance Menu (Technical menu screen 21: Maintenance Menu).

By pressing on the **Back** button, you can go to the Main Menu screen.

- **Technical Menu screen 4 : Settings menu**

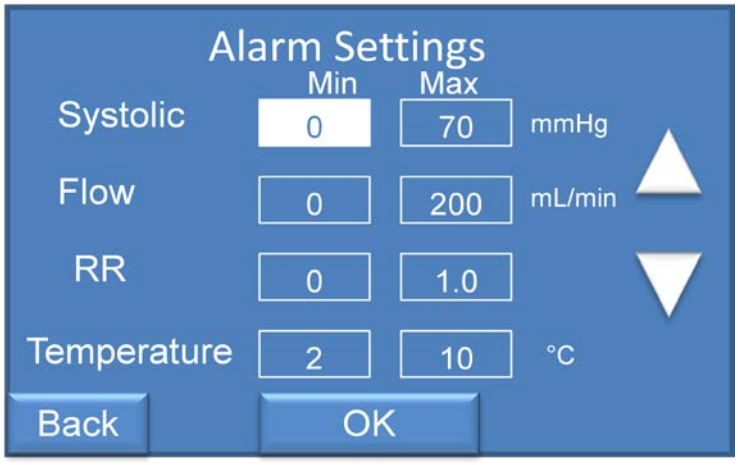


This screen is displayed when you press Settings button on the Technical Menu screen 3: Menu.

- Alarms Settings button to go to the Technical menu screen 5: Settings-Alarms settings 1.
- Languages button to go to the Technical menu screen 7: Settings-Language.
- Owner/password button to go to the Technical menu screen 8: Settings-Owner/Password.
- Date and Time button to go to the Technical menu screen 12: Settings-date and clock.
- Networking button to go to the Technical menu screen 13: Settings-Networking.
- Pressure/flow button to go to the Technical menu screen 14: Settings-Pressure/flow 1.
- Temperature button to go to the Technical menu screen 20: Settings-Temperature

By pressing **Back** button you can go to the previous step, Technical Menu screen 3: Menu.

- **Technical Menu screen 5 : Settings-Alarms settings 1**



This screen is displayed when you press Alarms settings button on the Technical Menu screen 4: Settings menu.

You can change the maximum and minimum accepted values (alarm values) for each following parameters: Systolic pressure (Systolic), Flow (Flow), Renal Resistance (RR), Perfusate Temperature (Temperature).

Select the parameter by pressing the value you want to change then use the arrows decrease or increase the value.

Press **OK** button to validate and go back to the Technical menu screen 6: Settings-Alarms settings 2.

Press **Back** button, you can go to previous step: Technical Menu screen 4: Settings menu.

- **Technical Menu screen 6 : Settings-Alarms settings 2**

This screen is displayed when you press on **OK** button on the Technical Menu screen 5: Settings-Alarms settings 1.

You have to confirm and cancel the modifications you made on the alarms settings.

Please press **NO** button to cancel the changes and go back to the Technical menu screen 5: Settings-Alarms settings 1.

Please press **YES** button to confirm your changes and go to the Technical menu screen 4: Settings menu and saves the modifications.

- **Technical Menu screen 7 : Settings-Language**

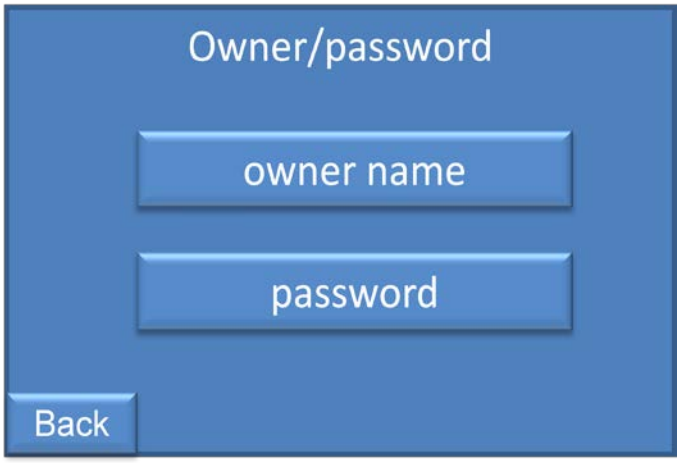
This screen is displayed when you press Languages button on the Technical Menu screen 4: Settings menu.

On this screen, you can change the language used in the device: English, French or Spanish.

Insert the USB flash memory with the languages into the USB port and then select the language by pushing on the corresponding button (English, Français, Espanol) and validate by pressing **OK** button.

By pressing the **Back** button you can go to the previous step: Technical Menu screen 4: Settings menu.

- **Technical Menu screen 8 : Settings-Owner/Password 1**



This screen is displayed when you press Owner/password on the Technical Menu screen 4: Settings Menu.

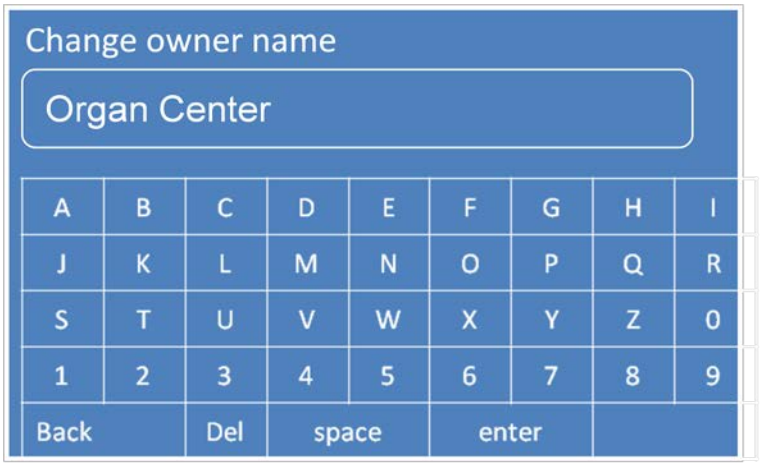
Choose to change the owner name or the password.

Pushing **Owner name** button goes to the Technical Menu screen 9: Settings-Owner/password 2.

Pushing **Password** button goes to the Technical Menu screen 10: Settings-Owner/password 3.

Pushing **Back** button goes to Technical Menu screen 4: Settings Menu.

- **Technical Menu screen 9 : Settings-Owner/Password 2**



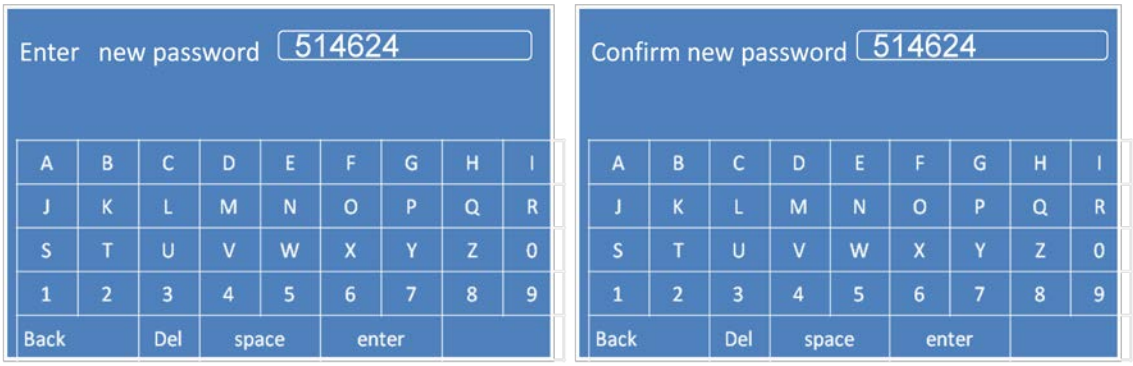
This screen is displayed when you press Owner name button on the Technical Menu screen 8: Settings-Owner/password 1.

The actual owner name is displayed. You can change the owner name using the keypad and press Enter to validate.

Pressing **Enter** validates the new owner name and goes to the screen Technical Menu screen 8: Settings-Owner/password 1.

Pressing **Back** you can go to the previous step: Technical Menu screen 8: Settings-Owner/password 1, without validating the new owner name.

- **Technical Menu screen 10 : Settings-Owner/Password 3**


Enter new password 514624
A B C D E F G H I
J K L M N O P Q R
S T U V W X Y Z 0
1 2 3 4 5 6 7 8 9
Back Del space enter
Confirm new password 514624
A B C D E F G H I
J K L M N O P Q R
S T U V W X Y Z 0
1 2 3 4 5 6 7 8 9
Back Del space enter

This screen is displayed you press Change password button on the Technical Menu screen 8: Settings-Owner/password 1.

You can change and confirm your password (password needed to access to the technical menu).

Please enter the new password and press **Enter**, then confirm this new password by entering it a second time and press Enter to validate and go to the Technical Menu screen 8: Settings-Owner/password 1, if the 2 passwords match. We recommend writing this new password down.

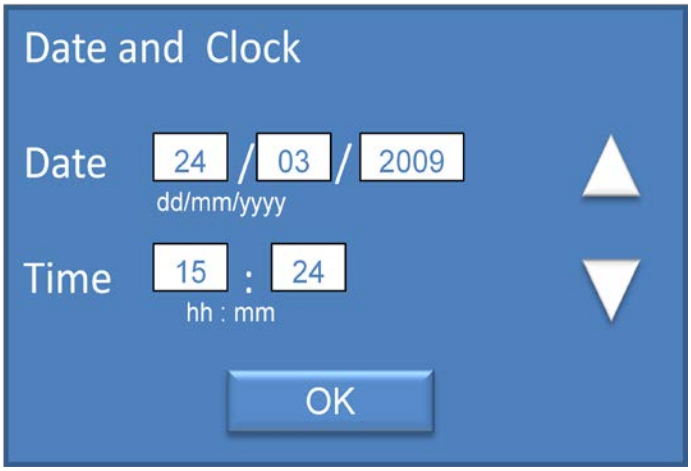
Pressing the **Back** button you can go to the previous step: Technical Menu screen 8: Settings-Owner/password 1.

- **Technical Menu screen 11 : Settings-Owner/Password 4**

This screen is displayed when you press **Enter** button if the 2 new passwords don't match on the Technical Menu screen 10: Settings-Owner/password 3.

Please press **OK** to enter the passwords again: Technical Menu screen 8: Settings-Owner/password 3.

- **Technical Menu screen 12 : Settings-date and clock**

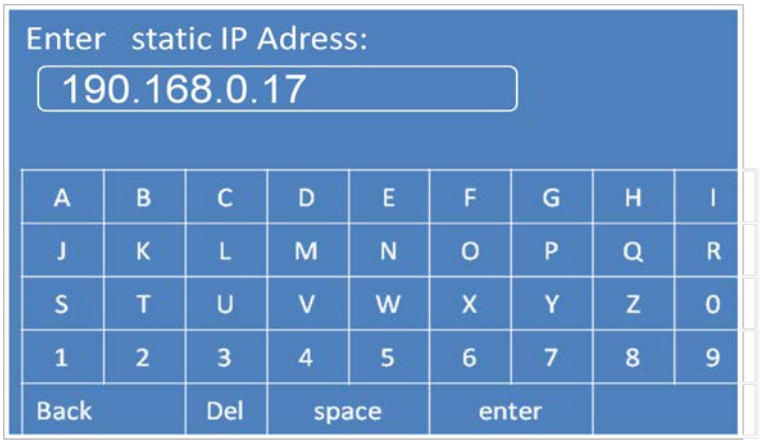


This screen is displayed when you press Date and Time button on the Technical Menu screen 4: Settings menu.

You can change the Date and the Time.

Select the value to change by pressing on the value to change and then the arrows to increase or decrease the value then press **OK** button to validate the modification and go to the Technical Menu screen 4: Settings menu.

- **Technical Menu screen 13 : Settings-Networking**



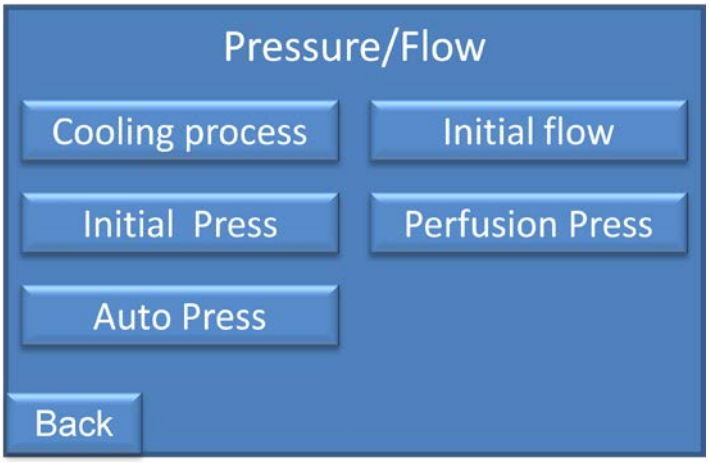
This screen is displayed when you press Networking button on the Technical Menu screen 4: Settings menu.

This section permits you to change if necessary the IP address of the WAVES control unit for networking communication. You may require assistance from your network administrator.

Please enter the IP address and push Enter button to validate

Pushing **Back** button you can go back to the previous step: Technical Menu screen 4: Settings menu.

- **Technical Menu screen 14 : Settings-Pressure/Flow 1**

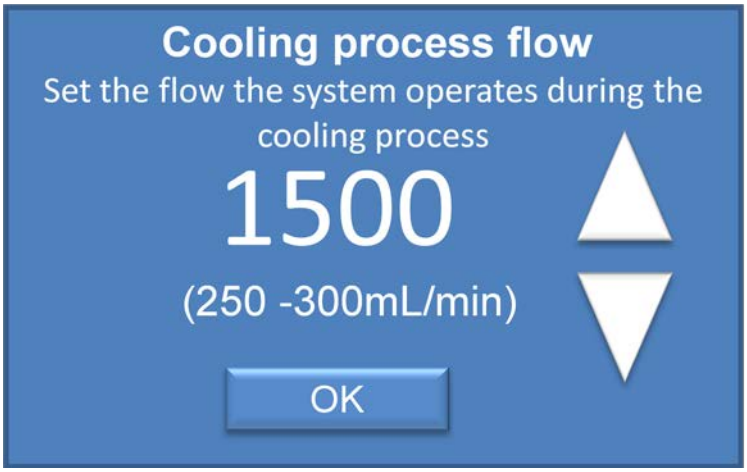


This screen is displayed when you press Press/flow button on the Technical Menu screen 4: Settings menu.

Please select the section you want to set the value you need:

- Pushing Cooling process button, goes to the Technical Menu screen 15: Settings-Pressure/Flow 2.
- Pushing Initial stroke button goes to the Technical Menu screen 16: Settings-Pressure/flow 3.
- Pushing Initial Press button goes to the Technical Menu screen 17: Settings-Pressure/flow 4.
- Pushing Perfusion Press button goes to the Technical Menu screen 18: Settings-Pressure/flow 5.
- Pushing Auto Press button goes to the Technical Menu screen 19: Settings-Pressure/flow 6.
- Pushing Back button goes back to the previous step: Technical Menu screen 4: Settings menu.

- **Technical Menu screen 15 : Settings-Pressure/Flow 2**



This screen is displayed when you press on Cooling Process button on the Technical Menu screen 14: Settings-Pressure/flow 1.

Please set the stroke value corresponding to the flow value the system will operate during the cooling process and press **OK** to validate

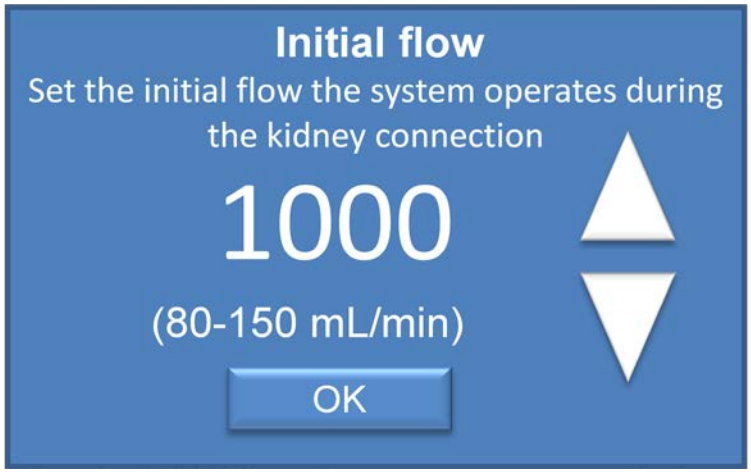
You can increase or decrease the stroke by pushing on the up or down arrow.

The system displays the value of the stroke (target) and the value of the associated estimate flow

Stroke = 0 to 200 : flow =0-1 mL/min
Stroke= 300 to 500 : flow= 0-10 mL/min
Stroke = 600 to 800 : flow = 20-80 mL/min
Stroke= 900 to 1100 : flow = 80-150mL/min
Stroke =1200 to 1400 : flow = 150-230 mL/min
Stroke = 1500 to 1700 : flow = 250-300 mL/min
Stroke= 1800-2000 : flow = 310-350 mL/min
Stroke > 2000 : flow = 350-400mL/min

Pushing **OK** button validates this value and goes to the Technical Menu screen 14: Settings-Pressure/flow 1.

- **Technical Menu screen 16 : Settings-Pressure/Flow 3**



This screen is displayed when you press Initial stroke button on the Technical Menu screen 14: Settings-Pressure/flow 1.

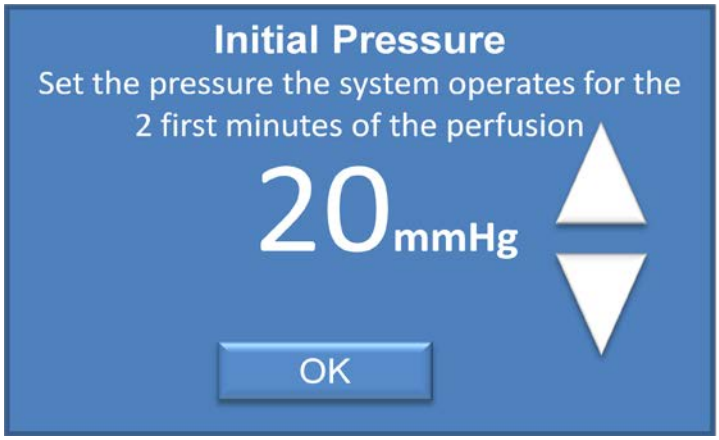
Please set the stroke/flow the system will operate during the kidney connection and until the beginning of the perfusion (Perfusion main Screen).

The system displays the value of the stroke (target) and the value of the associated estimate flow (TBD during the final validation).

Stroke = 0 to 200 : flow =0-1 mL/min
Stroke= 300 to 500 : flow= 0-10 mL/min
Stroke = 600 to 800 : flow = 20-80 mL/min
Stroke= 900 to 1100 : flow = 80-150mL/min
Stroke =1200 to 1400 : flow = 150-230 mL/min
Stroke = 1500 to 1700 : flow = 250-300 mL/min
Stroke= 1800-2000 : flow = 310-350 mL/min
Stroke > 2000 : flow = 350-400mL/min

You can increase or decrease the flow by pushing on the up or down arrow and push OK button to validate this value and go to the Technical Menu screen 14: Settings-Pressure/flow 1.

- **Technical Menu screen 17 : Settings-Pressure/Flow 4**



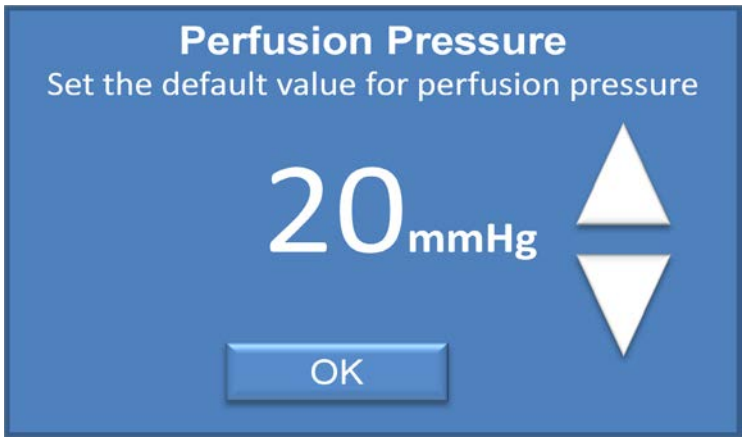
This screen is displayed when you press Initial pressure button on the Technical Menu screen 14: Settings-Pressure/Flow 1.

Please set the initial systolic perfusion pressure the system will operate during the first two minutes of the perfusion (when the system first arrives on the Perfusion main screen).

This value is also the maximum value of systolic pressure that the system has to operate during the kidney connection.

You can increase or decrease the pressure by pushing on the up or down arrow and push **OK** button to validate and go to the Technical Menu screen 14: Settings-Pressure/Flow 1.

- **Technical Menu screen 18 : Settings-Pressure/Flow 5**

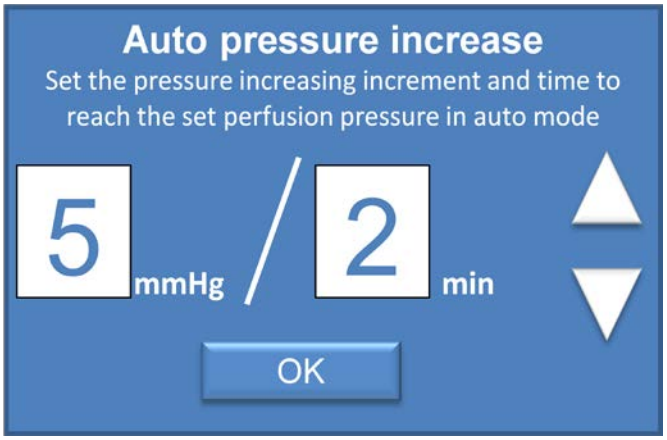


This screen is displayed when you press Perfusion Pressure button on the Technical Menu screen 14: Settings-Pressure/Flow 1.

Please set the default value of the perfusion pressure, which is displayed on Clinical screen 15: set perfusion pressure (Software specifications).

You can increase or decrease the pressure by pushing on the up or down arrow and push **OK** to validate and goes to the Technical Menu screen 14: Settings-Pressure/Flow 1.

- **Technical Menu screen 19 : Settings-Pressure/Flow 6**

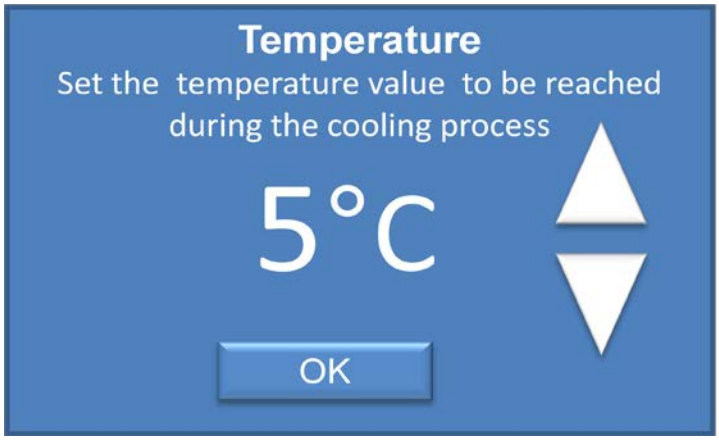


This screen is displayed when you press Auto Press button on the Technical Menu screen 14: Settings-Pressure/Flow 1.

Please set the rate (in mmHg/min) of increase in pressure when the system is in Auto Pressure Control Mode, using the down and up arrows, and press **OK** to validate and goes to the Technical Menu screen 14 : Settings-Pressure/Flow 1.

In Auto Mode, the system uses this rate to increase the pressure each time you change the set perfusion pressure.

- **Technical Menu screen 20 : Settings-Temperature**

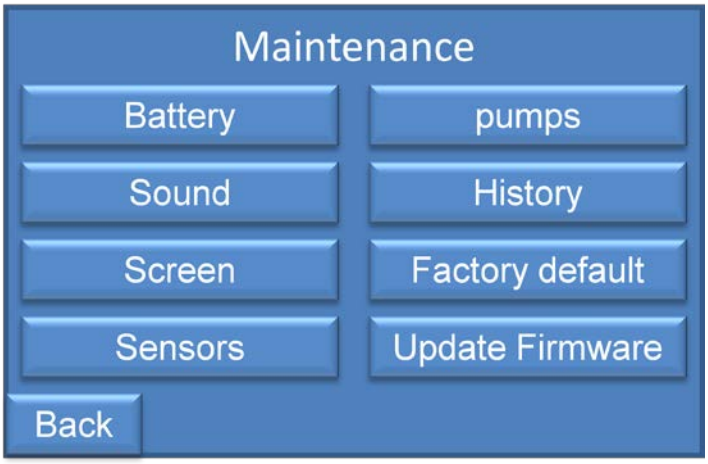


This screen is displayed when you press Temperature button on the Technical Menu screen 4: Settings menu.

Please set the value of the temperature using the up and down arrows and press **OK** button to validate and go to the Technical Menu screen 4: Settings menu.

The system will regulate the temperature at this value during the initial cooling process and all clinical perfusion processes (set value +/- 0.5°C).

- **Technical Menu screen 21 : Maintenance : Menu**



This screen is displayed when you press Maintenance button on the Technical Menu screen 3: Menu.

Pushing **Battery** button goes to the Technical menu screen 22: Maintenance: Battery 1.

Pushing **Sound** button goes to the Technical menu screen 23: Maintenance: Sound.

Pushing **Screen** button goes to the Technical menu screen 24: Maintenance: Screen 1.

Pushing **Sensors** button goes to the Technical menu screen 28: Maintenance: Sensors.

Pushing **Pumps** button goes to the Technical menu screen 29: Maintenance: pumps.

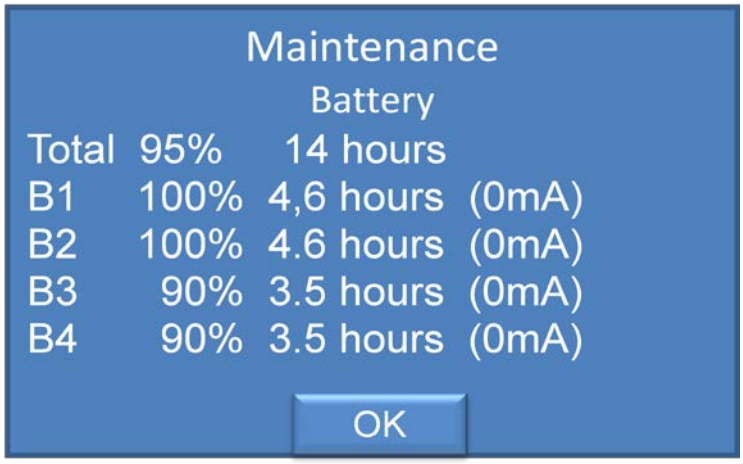
Pushing **History** button goes to the Technical menu screen 30: Maintenance: History Menu.

Pushing **Factory** Default goes to technical menu screen 33: Maintenance: Factory Default

Pushing **Update Firmware** goes to technical menu screen 34: Maintenance: Update Device Firmware 1.

Pushing **Back** button goes back to Technical Menu screen 3: Menu.

- **Technical Menu screen 22 : Maintenance : Battery**

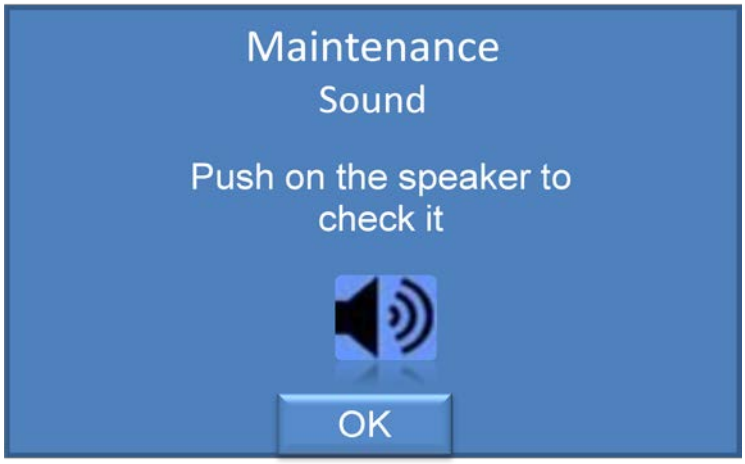


This screen is displayed when you press **Battery** button on the Technical Menu screen 21: Maintenance: Menu.

You can check each battery's charge (percentage and remaining hours).

Pushing **OK** button goes to Technical Menu screen 21: Maintenance: Menu.

- **Technical Menu screen 23 : Maintenance : Sound**



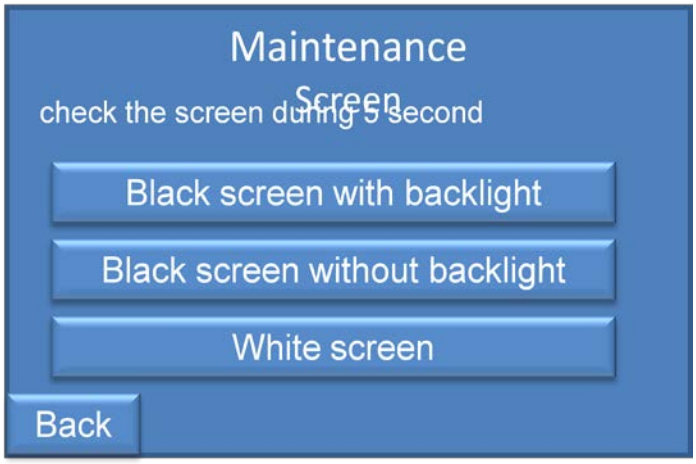
This screen is displayed when you press **Sound** button on the Technical Menu screen 21: Maintenance: Menu.

You can check the speaker of the device used for the alarms and the system.

Please press the speaker symbol to activate the speaker.

Pushing **OK** button goes to Technical Menu screen 21: Maintenance: Menu.

- **Technical Menu screen 24 : Maintenance : Screen 1**



This screen is displayed when you press Screen button on the Technical Menu screen 21: Maintenance: Menu.

You can check the screen of the device by pushing each of the buttons. The following screens permit you to detect any damage on the display.

Pushing the **Black screen with backlight** button goes to the Technical Menu screen 25: Maintenance: Screen 2.

Pushing the **Black screen without backlight** button goes to the Technical Menu screen 26: Maintenance: Screen 3.

Pushing the **White screen** button goes to the Technical Menu screen 27: Maintenance: Screen 4.

Pushing **Back** button goes to Technical Menu screen 21: Maintenance: Menu.

- **Technical Menu screen 25 : Maintenance : Screen 2**

This screen is displayed when you press Black screen with backlight button on the Technical Menu screen 26: Maintenance: Screen 1.

You can check any failure of the screen on the device on a black background with backlight.

The display keep this screen during 5 seconds and goes automatically to Technical Menu screen 26: Maintenance: Screen 1.

- **Technical Menu screen 26 : Maintenance : Screen 3**

This screen is displayed when you press Black screen without backlight button on the Technical Menu screen 26: Maintenance: Screen 1.

You can check any failure of the screen on the device on a black background without backlight.

The display keep this screen during 5 seconds and goes automatically to Technical Menu screen 26: Maintenance: Screen 1.

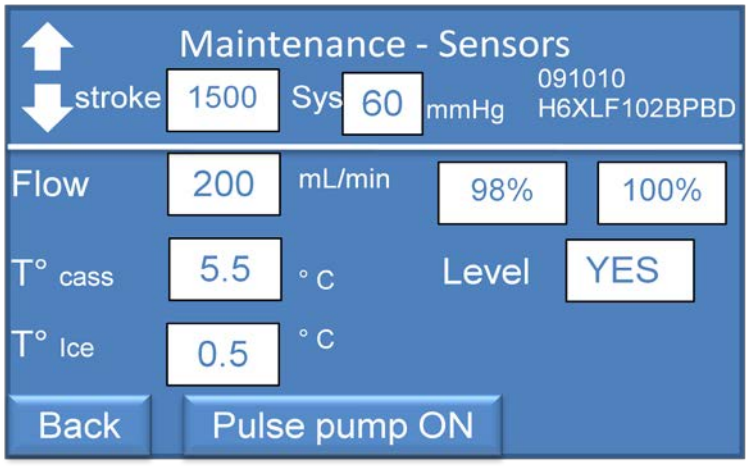
- **Technical Menu screen 27 : Maintenance : Screen 4**

This screen is displayed when you press White Screen button on the Technical Menu screen 26: Maintenance: Screen 1.

You can check any failure of the screen on the device on a white background.

The display keep this screen during 5 seconds and goes automatically to Technical Menu screen 26: Maintenance: Screen 1.

- **Technical Menu screen 28 : Maintenance : Sensors**



This screen is displayed when you press Sensors button on the Technical Menu screen 21: Maintenance: Menu.

You can check the good state and calibration of the pressure sensor, flowsensor (Flow), the cassette temperature sensor (Temp1), the ice container temperature sensor (Temp2) and the ice container liquid level sensor (Level).

Please select the stroke value of the pulse pump with the △ UP and ▽ DOWN arrows.

You can read the value of pressure, flow, cassette temperature and ice container temperature.

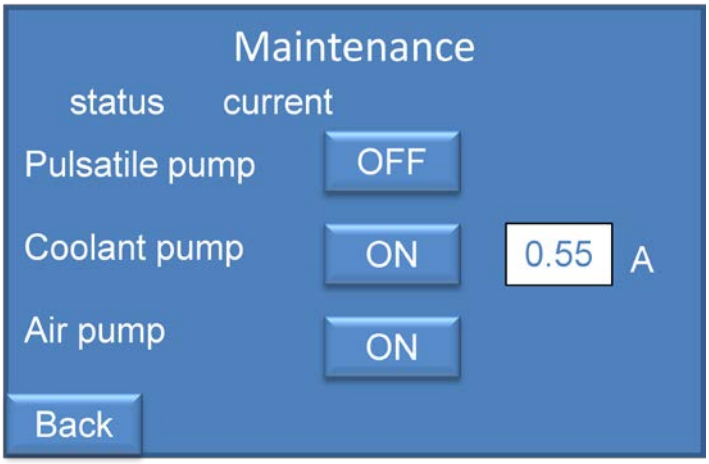
You can turn the pulse pump on or off by pressing the Pulse pump ON or Pulse pump Off button

You need to place and lock a cassette to begin obtaining measures of flow and temperatures (pulse pump On).

If the sensors are not detected (cassette not in place), only a white box with a horizontal dash is displayed

Pressing **Back** goes to Technical Menu screen 21: Maintenance: Menu.

- **Technical Menu screen 29 : Maintenance : Pumps**



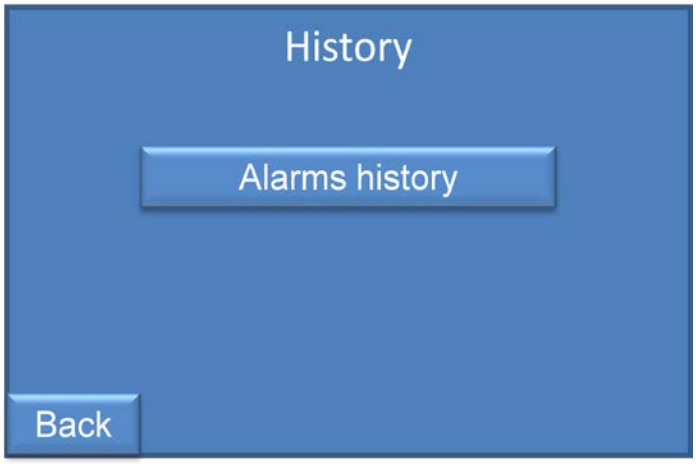
This screen is displayed when you press Pumps button on the Technical Menu screen 21: Maintenance: Menu.

You can check the good state of the coolant, pulsatile or air pump by turning them ON or OFF, and check the current of the coolant pump.

If the coolant pump current value exceeds 1.00 A continuously the pump requires replacing.

Pushing Back goes to Technical Menu screen 21: Maintenance: Menu.

- **Technical Menu screen 30 : Maintenance : History Menu**



This screen is displayed when you press History button on the Technical Menu screen 21: Maintenance: Menu.

You can view the history of the alarms by pressing the **Alarms history** button. See the Technical Menu screen 31: Maintenance: History-Alarms.

Pushing **Back** button goes to Technical Menu screen 21: Maintenance: Menu.

- **Technical Menu screen 31 : Maintenance : History-Alarms**

This screen is displayed when you press Alarms History button on the Technical Menu screen 32: Maintenance: History Menu.

You can scan the alarms occurred during the corresponding perfusion.

Pressing ⇧ UP or ⇩DOWN arrow, you can scan all alarms classified by date and time.

Pressing **OK** button goes to Technical Menu screen 30: Maintenance: History Menu.

Pressing **Back** button goes to Technical Menu screen 30: Maintenance: History Menu.

- **Technical Menu screen 32 : Maintenance : Factory Default**

This screen is displayed when you press **Factory Default** button on the Technical Menu screen 21: Maintenance: Menu.

Pressing **NO** cancels this action and goes back to Technical Menu screen 21: Maintenance: Menu.

Pressing **YES** validates this action and erases all the data from the device, then go to Technical Menu screen 21: Maintenance: Menu.

- **<u>Technical Menu screen 33 : Maintenance : Update Device Firmware 1</u>**

This screen is displayed when the user presses **Update Device Firmware** button on the Technical Menu screen 21: Maintenance: Menu.
Pressing **No** to cancel this action and goes back to Technical Menu screen 21: Maintenance: Menu.
Pressing **Yes** to validate this action and check if a USB flash drive is connected.

- **Technical Menu screen 34 : Maintenance : Update Device Firmware 2**

This screen is displayed when the user presses **Yes** button on the Technical Menu screen 34: Maintenance: Update Device Firmware 1.
The WAVES is checking the connection of USB flash drive and searching for a new firmware version.
If the USB is detected, the Technical Menu screen 36: Maintenance: Update Device Firmware 3 is displayed.
If not a message box appears: Technical Menu screen 38: Maintenance: Update Device Firmware 5.

- **Technical Menu screen 35 : Maintenance : Update Device Firmware 3**

This screen is displayed when the USB connection is detected.
Pressing **No** to cancel this action and goes back to Technical Menu screen 34: Maintenance: Update Device Firmware 1.
Pressing **Yes** to validate the action and start the firmware update.

- **<u>Technical Menu screen 36 : Maintenance : Update Device Firmware 4</u>**

This screen is displayed when the user presses **Yes** on Technical Menu screen 36: Maintenance: Update Device Firmware 3.

This screen is displayed during 5 seconds before the Waves reboots. While the WAVES is loading the new software ***<u>do not turn the unit off</u>***. If the power fails during this operation the programming will be incomplete and the unit will be inoperable and the unit will need to be returned to Waters for re-programming.

- **Technical Menu screen 37 : Maintenance : Update Device Firmware 5**

This screen is displayed when no USB flash drive is detected on Technical Menu screen 35: Maintenance: Update Device Firmware 2.

Pressing **OK** goes back to Technical Menu screen 34: Maintenance: Update Device Firmware 1.

PARAMETER MEASUREMENT RANGE

Parameter	*Range*	*Displayed Range*	*Low Alarm limit (factory default)*	*High Alarm limit (factory default)*
Systolic Pressure (mmHg)	**0-100**	**0- 100**	**0**	**70**
Flow (ml/min)	**0-250**	**0-250**	**0**	**200**
Renal Resistance	**0-9.99**	**0-9.99**	**0**	**1.0**
Perfusate Temperature	**3° - 10°C**	**0° - 30°C**	**2°C**	**10°C**

MAINTENANCE

Please call WMS technical support for all questions or problems.

Do not try to open the WAVES technical zone covers or repair the WAVES.

Opening this cover will negate the manufacturer's warranty.

PULSE PUMP

The pulse pump requires no periodic maintenance. If failure occurs, consult the WMS Customer Service (see page 2).

CLEANING AND STERILIZATION OF TRANSONIC® FLOWPROBES

The Transonic flowprobe installed in the cassette chamber of the WAVES control unit cannot be removed from the WAVES control unit. If failure occurs, consult the WMS Customer Service (see page 2).

BATTERY SHELF LIFE & STORAGE

- The WAVES system has four smart LI-Ion batteries.
- Each battery's nominal operating voltage is 10.8V.
- The smart battery should be stored in a well-ventilated environment with low humidity, free from corrosive gas at a recommended temperature range <21°C.
- Extended exposure to temperatures above 45°C could degrade battery performance and life.
- Storage Temperature Limits: -20°C to 60°C, 80% RH.
- Do not immerse the batteries in water.
- Do not disassemble or deform the battery.
- Do not expose to, or dispose of the battery in fire.
- Avoid excessive physical shock or vibration.
- Never use a battery that appears to have suffered abuse.
- Battery must be charged in appropriate charger only (dedicated level II or level III smart battery charger. Never use a modified or damaged charger.
- The fuel gauge on the back of each battery determines the state of charge.
- Do not short the battery.
- Calibration is the process whereby the battery's fuel gauge is adjusted to maintain an acceptable level of accuracy. This may be necessary if a battery has aged or has been subjected to an unusual usage pattern. Please proceed to the calibration with an adequate charger or call WMS technical support.
- Regulations vary for different countries. Dispose of battery in accordance with local regulations.

STORAGE

Drain the ice chamber completely. See Cleaning section on page 133.

Remove the cassette, if any, from the cassette chamber and dispose of properly.

Store the WAVES in a dry, room temperature environment in the Waves transport bag for protection.

For long-term storage, remove batteries and drape the transport bag and unit with a plastic sheet.

SHIPPING

To return the WAVES control unit for maintenance (periodic or corrective), use adequate packaging materials provided by Waters Medical Systems.

You can use a common transport company.

Before shipping:

- Clean the WAVES control unit as described in the Cleaning section on page 133 to avoid contamination.
- Check the ice compartment and make sure it is empty and dry.
- Remove the ice compartment lid.
- Check the battery door is properly close.
- Remove any old cassette.
- Check the device is turned OFF.
- Secure the WAVES in the shipping box.
- Disconnect any cable (network, power, USB) and components (USB flash drive).

CLEANING

The WAVES cabinet should be cleaned after each use.

First turn off the WAVES and disconnect the power.

Clean the WAVES using a soft cotton cloth and mild detergent, such as dish soap or hydrogen peroxide and warm water.

Occasionally, the ice compartment and pump should be cleaned using 10% household bleach solution. This process is completed by running 250 ml of 10% bleach solution through the reservoir pump using the "drain machine" command to prevent mold. Once the solution is completely pumped out through the drain line, the reservoir should be wiped out with a dry cloth and left open to air dry.

If a commercial bactericide is used, such as Cidex®, test on an inconspicuous part of the cabinet to determine there is no damage or stain to the paint.

CAUTION: Never use the following for cleaning the WAVES or permanent damage may occur to the finish or cabinet:

- DO NOT USE >10% chlorine bleach and water solution
- Solvents such as methyl or ethyl alcohols, acetone, trichloroethane, trichloroethylene, Freon® or denatured ethanol.

After each use, the coolant tank should be drained and a disinfectant used to rinse out the container. The coolant tank should be stored dry.

PRACTICE

Practice setup and perfusion techniques using human "research" organs with proper paperwork and permission or, use animal kidneys, with appropriate paperwork and permission to become familiar with the kidney perfusion using the WAVES system.

Use aseptic techniques to avoid any contamination.

Place the kidney and the arteries in adequate position to avoid any kink or damage.

Cannulate properly to avoid any leaks.

Select adequate perfusion pressure to avoid damage of the kidney.

NEVER leave the device unattended.

APPENDIX A: SPECIFICATIONS

Product Definition	Specification
Device classification	FDA : Class II Medical Device CE : Class IIA Electric : Class I
Technologies Applied in End Function	Pulsatile Perfusion Oxygenator Hypothermic Control Micro Processor Control and data acquisition Network monitoring
Environment of use	Organ Procurement Organizations (OPO), hospitals
User	Used by OPOs, hospitals, and in other clinical environments. Operators should be specially trained in organ preservation.
Product Life	Control unit: 10 years after manufacturing release Disposable: 2 years shelf-life after sterilization
Associated products	Machine preservation solution for kidneys Clamps and Cannula for attaching kidneys Sterile drape and specimen containers Devices for network connectivity such as wireless routers USB memory devices for transporting preservation history data. Wheeled Transport Bag
Portability	Yes 24 hours operation on battery
Environmental Limits	Temperature 0° to 40° Humidity : 0% to 95% non-condensing Pressure : 94 to 101 kPa Elevation: sea level to 2000’
Hypothermic kidney operation	Temperature controlled 3° to 10°C Operation on ice : 24 hours (10° max at 21° ambient) with an extra ice filling Power failure failsafe hypothermic preservation for 12 hours
Perfusion	Pulsatile 60 pulses per minute fixed Pressure regulated or fixed 0 to 250 ml/min perfusion flow
Air pump	Ambient air for oxygenation. 1.5-2 L/M External gas inlet port available. (local protocol approved)
Display / User Interface	Low power LCD 4.3” color display LED backlight

	Integrated touch panel
Cooling	Ice and water circulated in a closed cooling circuit using thermal transfer to perfusate Ice/water compartment capacity: 5 Liters Easy ice entry access Easy drainage Coolant container sealed to prevent leakage Coolant pump: 12 Volts DC non submersible
Enclosure	Molded fiberglass enclosure UL94V-O flammability rating
Power	100-240VAC, 50-60 Hz, medical grade universal power supply. 4 Li-Ion batteries for transportability and battery backup. Battery compartment easily accessible on the back. Built-in charger for batteries. Both main line circuit breakers.
Flow measurement	Transonic flowmeter board built into the WAVES. Transonic flowprobe attached to the WAVES.
Pressure measurement	Disposable medical pressure sensor on the cassette.
Temperature measurement	Perfusate: disposable RTD sensor on the cassette. Ice/water: non disposable RTD sensor in the ice compartment.
Levels of Accuracy for Functionality	Pressure display ±1.0 mmHg Temperature display ±0.5°C Flow display ±7% Renal resistance display calculated
Measured limits: Flows, pressures, Temperature	Pressure: 0 to 100 mmHg Temperature: 0 to 40°C Flow: 0 to 250 ml/min
Interfaces with systems	Ethernet network connectivity.
Data Storage/Outputs	Internal 2 MB non-volatile memory. USB for memory device for data history transfer.
Size (Envelope)	25 ½" x 16 ¼" x 13 ¼" (648 mm x 413 mm x 337 mm)
Weight	WAVES System : 26 kg fully loaded.
Lifetime of the product(s)	10 years.

APPENDIX B: BLOCK DIAGRAM

The Functional Diagram describes the operation of the WAVES monitor and the WAVES cassette.

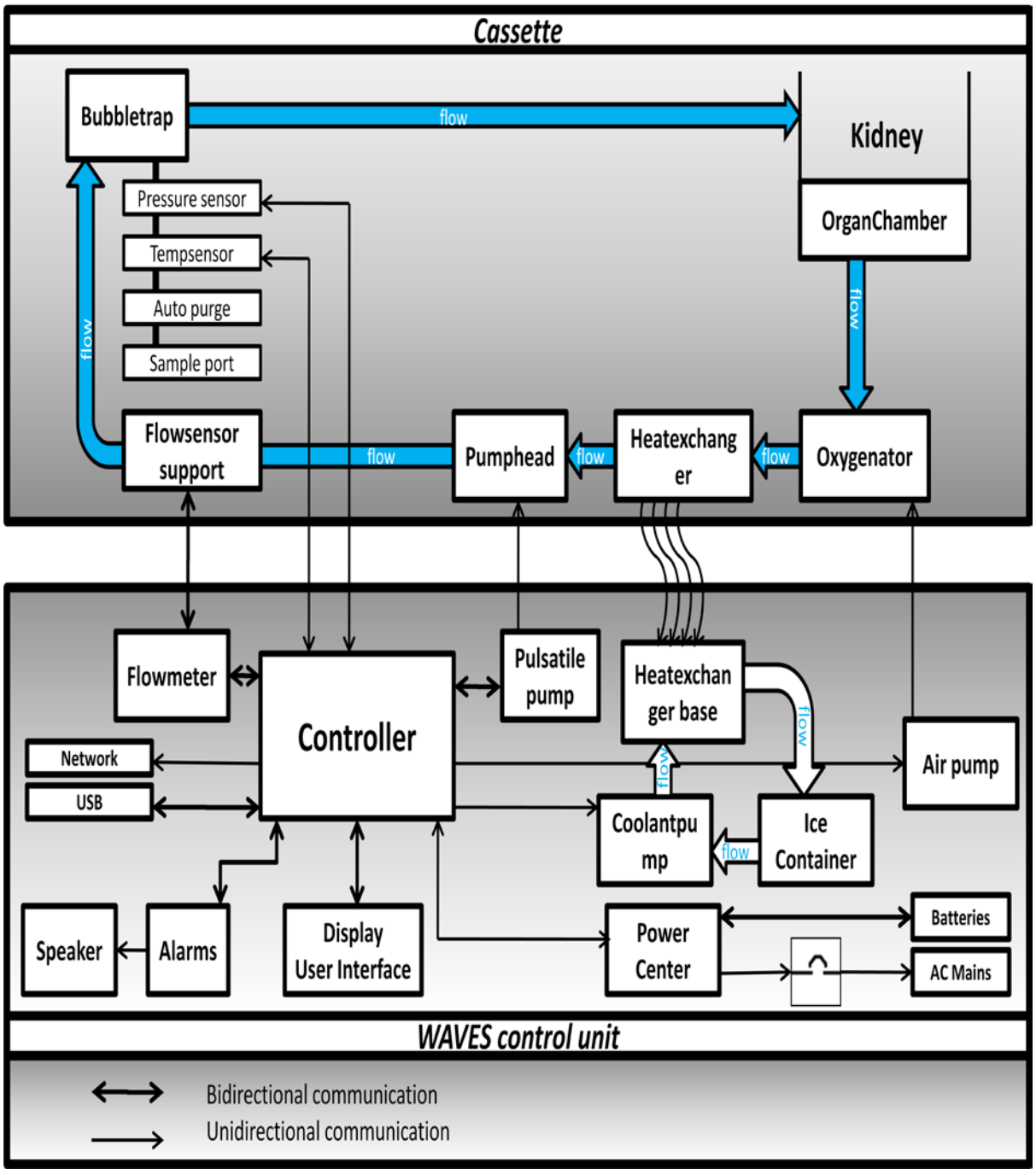


Figure 20: **WAVES block diagram**

Controller / Alarm
The controller directs all components of the system to be able to measure, display and store parameters. The controller also includes a clock. The readings are compared with alarm limits, visual and audible alarms are triggered if the limits are exceeded.

Display/User Interface
The Touchpad display allows you to follow the perfusion protocol and adjust the pulse pump rates (by changing the systolic pressure).

It permits one to enter all perfusion data and parameters such as user name, perfusion number, set perfusion pressure, and pressure regulation mode. The display also shows the perfusion data (systolic pressure, diastolic pressure, main pressure, flow, renal resistance, perfusate temperature, battery charge level…) in real time.

The user can note when an alarms occurs (alarm message box and highlighted values), and one has access to different graphic and numeric representations of data (flow, pressure, temperature, renal resistance) The user interface allows one to save or transfer data by USB or network.

Audio Alarm
The alarm sounds in the event of an alarm condition. The audio alarm may be suspended under user control.

Power Center
The power center includes medical grade power supply, battery charger, signal and power distribution functions. The power center also has an automatic hierarchical power source switching system. The power center accepts power from AC mains, and 10.8 Volts Li-Ion batteries.

Pulsatile Pump
The pulsatile pump rate (pulse per minute) is fixed by software at 60ppm. You can change the level of compression (stroke volume) of the silicon pumphead only by software update (by changing the pressure value).

Cooling System
The cooling system includes an ice water reservoir, a coolant pump, a heat exchanger and a heat exchanger base. The pump, controlled by software, is cycled on and off to control the perfusate temperature.

Cassette Connection
The Cassette connection is made by the cassette cable receptacle. It permits the connection of the cassette cable connector to have access of the perfusate temperature and the pressure data provided by the disposable temperature and pressure sensors placed on the bubble trap.

Air Pump
The air pump is used to blow room air through the oxygenator chamber. This air pump is activated when the pulse pump is turned on.

One can also blow other gases such as oxygen using the external gas inlet port if approved by local protocol.

APPENDIX C: FLOW MEASUREMENT

Measuring flow with the WAVES

The WAVES system uses a TRANSONIC flow measurement system to measure the flow across the cassette tubing. In this manner, sterile perfusate does not come in contact with the flowprobe. The flowprobe is non-removable. It uses a real-time ultrasound signal method to insure precision measurements.

How the Flowprobe Work

The Transonic flowprobe uses the transit time ultrasound method to accurately measure perfusate flow. The flowprobe incorporates two transducers that generate ultrasonic beams which alternately intersect the perfusate. The difference between the upstream and downstream ultrasonic beam transit times is a measure of volume flow. The flowprobe is pre-calibrated for use with the WAVES and perfusate.

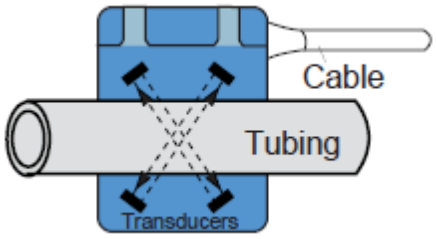
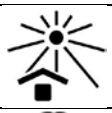


Figure 21: WAVES Flow Sensor

The WAVES will update the flow for the displayed value, trend and graph the data, and use this value in the renal resistance calculation.

Appendix **D: Graphic Symbol Index**

	Symbol for “CAUTION: Refer to accompanying documents”
	Symbol for "Batch Code".
	Symbol for "Date Of Manufacture".
	Symbol for “DO NOT REUSE”.
	Symbol for “Catalog number”.
	Symbol for “Serial Number”.
	Symbol for “Sterilized Using Ethylene Oxide”.
YYYY-MM	Symbol for “Use By”. Date referenced *Year – Month.*
	Symbol for “Manufacturer”.
	Symbol for product is classed as Electrical or Electronic Equipment and is covered by the WEEE Regulations. Please refer to
	Symbol for “KEEP DRY”.
	Symbol for “STORE OUT OF DIRECT SUNLIGHT”
	Symbol for “Consult Instructions For Use”.

WASTE ELECTRICAL AND ELECTRONIC EQUIPMENT (WEEE)

The Waste Electrical and Electronic Equipment Regulations (2006 No. 3289) (WEEE) have been put in place to ensure that products are recycled using best available treatment, recovery and recycling techniques to ensure human health and high environmental protection.

When you have finished with a WEEE product, **please do not** put in your domestic waste bin, as it will not be recycled.

To ensure that your WEEE is recycled in accordance with the regulations, you should ensure that the goods are not put in the bin, but are separately disposed of by taking the WEEE to your local designated collection facility. This would normally be your local civic amenity site (recycling center). You can find your local approved site.